which acts to urge the cartridge in a direction away from the needle, in conjunction with a releasable retention device bearing on the top rim of the cartridge. The spring arrangement may comprise a projection engageable with the resilient penetrable member of the cartridge, or an interposed spring means.

The invention will now be described further by way of example only and with reference to the accompanying drawings in which:

Fig. 1 is an axial section of a syringe provided with one form of a disposable housing in accordance with the invention; and

Figs. 2 & 3 are enlarged axial sections of a bottom part of the arrangement of Fig. 1 showing alternative embodiments thereof.

Referring to Fig. 1, the syringe comprises a plunger mechanism 1 (e.g. of stainless steel) having a body part 2 with a finger grip 3, a plunger 4 slidable axially through a bore in the body 2, and a barrel extension 5 coaxial with the plunger 4. The barrel extension 5 may comprise a tube, or apertured tube, or tubular framework.

At its forward end, the tubular extension 5 has an internal screw-thread 6.

A conventional drug-containing cartridge 7 is used with the syringe, such cartridge comprising a glass tube with a bung 8 within one (rearward) end and a foil covered penetrable membrane 9 across the other (forward) end. The glass tube is shaped to provide a circumferential groove 10 defining a neck close to the forward end.

A connection structure 11 is attached to the forward end of the cartridge 7. This structure 11 comprises a plastics body of cup-shaped form with a cylindrical part 12 which is closed at one end and has a central axially projecting boss 13 on its outer face.

There is a narrow axial bore through the closed end and the boss 13. The boss 13 and the cylindrical part 12 both have external screw-threads 14, 15.

The cylindrical part 12 has an open end bounded by an inturned lip 16.

There is sufficient resilience in the lip 16 and/or the associated body of the connection structure 11 to enable the structure to be pushed over the forward end of the cartridge 7 so that the lip 16 springs into, or snap fits with, the groove 10 thereby to retain the structure 11 securely on the end of the cartridge 7.

With the connection structure 11 in position the cartridge 7 can be inserted into the barrel extension 5 and held securely in position by screwing the thread 15 of the cylindrical part 12 into engagement with the screw thread 6 at the end of the barrel extension 5.

A conventional needle 17 can then be screwed on to the boss 13 so that its rear end penetrates the membrane 9.

In this position the rearward end of the cartridge 7 is at the rearward end of the barrel extension 5 and the bung 8 is close to the end of the plunger 4.

The syringe can now be operated in the usual way to cause the bung 8 to be displaced down the cartridge 7 with the plunger 4 to expel drug through the needle 17.

After use, the connection structure 11 is unscrewed from the barrel extension 5 so that the cartridge 7, connection structure 11, and needle 17 can be removed and disposed together.

It will be seen that the cylindrical part 12 of the connection structure 11 has a lower, or forward portion 18 which is not threaded and which remains outside the barrel extension 5 to provide a convenient finger grip for screwing and unscrewing the structure 11. This portion 18 may be enlarged or shaped as desired to further facilitate gripping.

As shown in Fig. 1 a tubular sleeve 19 may be engaged around the connection structure 11, such sleeve 19 being movable axially between a rearward limit position (as shown) at which it overlies the barrel extension 5 and fully exposes the needle 17, and a forward limit position at which it covers the needle 17.

The sleeve 19 is removed and disposed together with cartridge 7 and needle 17 with the sleeve 19 covering the needle 17 to avoid needle stick injuries.

The sleeve 19 has inwardly directed recesses 20 at each end which snap fit with projections 21 on the structure 11 to hold the sleeve 19 in each limit position. Also, the sleeve 19 may be internally longitudinally grooved to accommodate the projections 21 whereby the sleeve 19 is free

to move axially but cannot rotate relative to the structure 11. The rotation of the structure 11 relative to barrel extension 5 can therefore be effected by rotation of the sleeve 19.

With the arrangement described above, full advantages of disposability can be attained using a conventional cartridge.

As shown in the modified embodiment of Fig. 2, the structure 11 has an upstanding small projection 22 which presses against the penetrable membrane 9 at the end of the cartridge. At the top end of the syringe there is a suitable structure (indicated diagrammatically at 23 in Fig. 1) which bears against the top rim of the cartridge and holds the projection 22 pressed firmly into the membrane 9.

If this top end bearing structure 23 is now released, and pressure is released from the plunger 4, the cartridge will move slightly upwards due to the resilience of the membrane 9. This gives a very small suck-back or aspiration effect through the needle.

This is useful e.g. in dentistry where an injection is being made into soft gum tissue and it is desired to avoid penetration of a vein or artery. If penetration of a vein or artery has occurred the aspiration will cause blood to flow back into the cartridge.

Other resilient or spring arrangements may be used to achieve aspiration. Thus, Fig. 3 shows a modification in which the structure 11 is formed integrally with the needle 17. Springy transverse projections 24 or fingers are incorporated for resilient engagement with the bottom of the

cartridge.

It is of course to be understood that the invention is not intended to be restricted to the details of the above embodiment which are described by way of example only.

Thus, for example, the embodiment of Fig. 1 utilises a conventional needle and therefore has said connection structure 11 which is separate from the needle and is adapted to be interconnected thereto by means of the threaded boss 13. However, if desired, and as shown in Fig. 3, the structure 11 may be formed integrally with the needle so that it is supplied together with the needle.

Where the structure 11 is interconnected by means of the threaded boss 13 with a conventional needle, the structure 11 may be supplied with the needle, or ready fitted on the end of the cartridge or as a separate part to be fitted to the needle and to the cartridge prior to use.

The syringe may be as described adapted for end loading of the cartridge. It is however also possible to use a conventional side-loading syringe. The body of the syringe may be formed from plastics or stainless steel or any other suitable material or combination of materials as appropriate.

The interconnection between the structure 11 and the syringe body need not be through screw threads. Especially in the case of a rigid stainless steel syringe body, the interconnection may be achieved in the manner of a push-in or snap-fit or other clip type connection.

Depending on the nature of the syringe and the mode of location of the cartridge therewithin, the structure 11 need not clip around or otherwise connect positively to or even engage the end of the cartridge. The cartridge may be held within the body of the syringe in conventional manner e.g. after side loading thereof through the usual side slot or aperture.

CLAIMS

1. A detachable housing for a syringe comprising a drug-containing cartridge (7) having a bung (8) at one end and a penetrable member (9) at the other end, the cartridge being adapted for connection to a needle (17) at the said other end, such that the needle (17) penetrates the penetrable member (9), and being adapted for connection to a plunger mechanism (1) at the said one end, so that the bung (8) can be moved down the cartridge (7) to expel the drug through the needle (17), characterised in that the cartridge (7) is provided with at least one separate structure (11) attachable relative thereto, said structure (11) being adapted for the said connection of the cartridge (7) to the needle (17) and providing means for releasable connection to the plunger mechanism (1), whereby the housing comprising the cartridge (7), the (or each) said structure (11), and the needle (17) can be detached from the plunger mechanism (1) for disposal together.

2. A housing according to claim 1 characterised in that there is one said structure (11) which is attachable to the said other end of the cartridge (7) and which is adapted for connection to the needle (17) and which provides the means for connection to the plunger mechanism (1).

3. A structure for attachment to a drug-containing cartridge of a syringe, which cartridge (7) has a bung (8) at a rearward end and a penetrable membrane (9) at a forward end, said structure (11) being adapted for attachment to a needle (17) and having means (16) for attachment relative to the forward end of the cartridge, and means (15) for attachment to a

plunger mechanism (1).

4. A structure according to claim 3 characterised in that the means (16) for attachment to the forward end of the cartridge comprises means arranged to fit around a neck at the forward end of the cartridge.

5. A structure according to claim 3 or 4 characterised in that said structure (11) is formed integrally with the needle (17).

6. A structure according to claim 3 or 4 characterised in that said structure (11) is formed separately from the needle and incorporates means (13) for connection thereto.

7. A structure according to any one of claims 3 to 6 characterised in that the means (15) for attachment to the plunger mechanism (1) comprises an outer peripheral retaining structure adapted to mate with a corresponding retaining structure at the end of a barrel extension (5) on the plunger mechanism (1).

8. A structure according to any one of claims 3 to 7 characterised by the provision of a sleeve (19) which is mounted on the structure (11) for longitudinal movement forwardly to sheath the needle (17) after use.

9. A structure according to any one of claims 3 to 8 characterised by the provision of a spring arrangement (22 or 24) on the structure (11) which acts to urge the cartridge in a direction away from the needle (17), a releasable retention device (23) being provided to bear on the top rim of the cartridge to resist said urging of the spring arrangement.

10. A housing according to claim 1 or 2 when using the structure of any

one of claims 3 to 9.

1 / 2

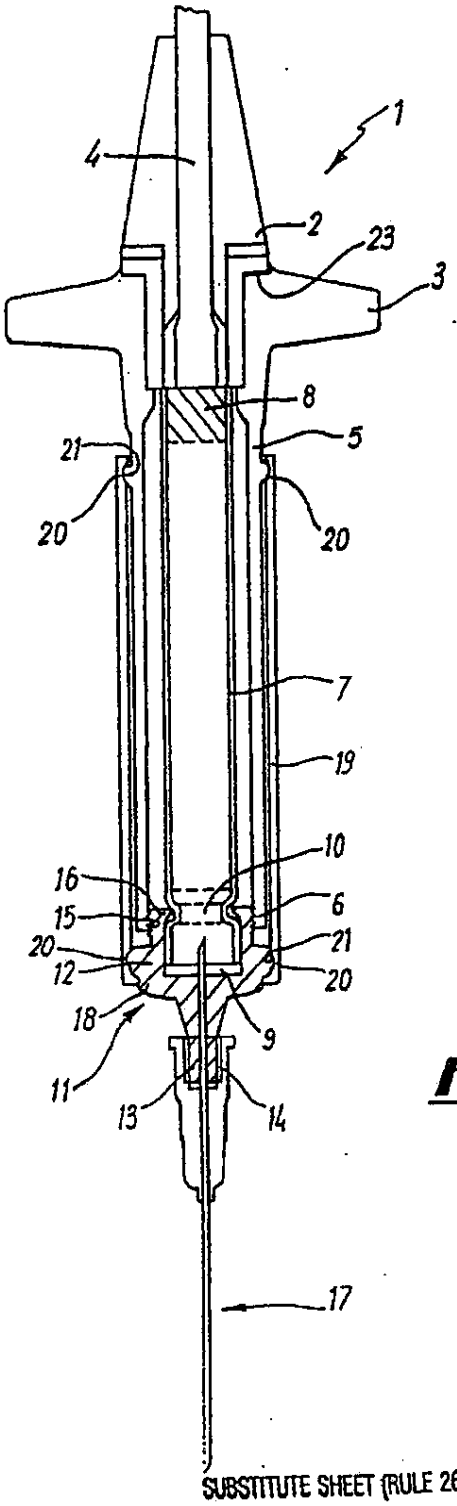

FIG. 1

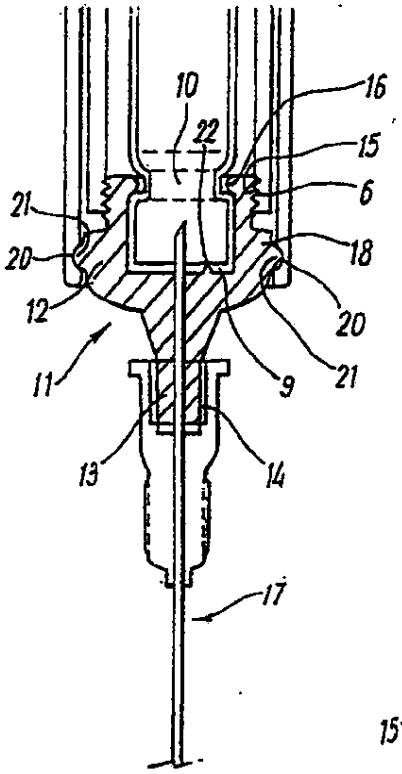
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FIG.2

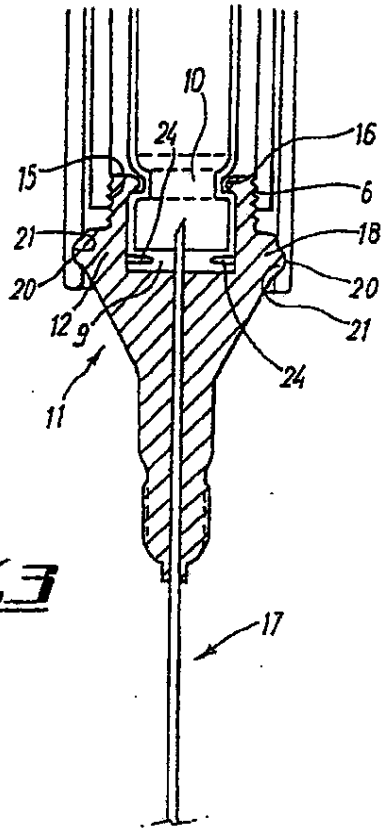
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FIG.3

INTERNATIONAL SEARCH REPORT

Inter- al Application No
PC:/GB 94/02475

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61M5/24

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	US,A,2 778 359 (FRIEDMAN) 22 January 1957 see column 4, line 20 - line 36; figures	1-7,10 8
Y	WO,A,89 04680 (SELDOREN LTD) 1 June 1989 cited in the application see abstract; figures	8
X	US,A,3 825 002 (PAIGE) 23 July 1974 see column 3, line 58 - column 4, line 15; figures	1-7,10
X	US,A,2 671 450 (DANN) 9 March 1954 see the whole document	1-7,10
X	US,A,3 080 866 (FRIEDMAN) 12 March 1963 see column 3, line 57 - column 4, line 9; figures	1-7,10

☐ Further documents are listed in the continuation of box C.

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Date of the actual completion of the international search	Date of mailing of the international search report
10 February 1995	0 9. 03. 95

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INTERNATIONAL SEARCH REPORT

Information on patent family members

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Patent document cited in search report	Publication date	Patent family member(s)		Publication date
US-A-2778359	22-01-57	NONE		
WO-A-8904680	01-06-89	DE-D-	3887531	10-03-94
		EP-A-	0394295	31-10-90
		GB-A-	2230193	17-10-90
US-A-3825002	23-07-74	NONE		
US-A-2671450	09-03-54	NONE		
US-A-3080866	12-03-63	NONE		

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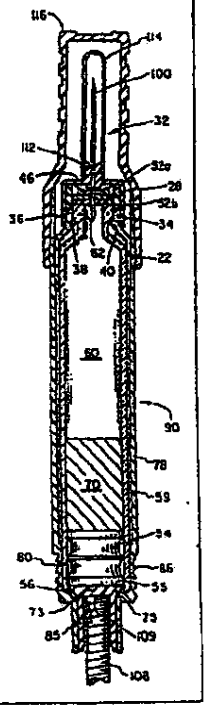
(54) Title: CARTRIDGE ASSEMBLY FOR A LYOPHILIZED COMPOUND FORMING A DISPOSABLE PORTION OF AN INJECTOR PEN AND METHOD FOR SAME

(57) Abstract

A cartridge assembly (90) for holding a lyophilized product, forming a disposable portion of a pen injector (104), includes a cylindrical glass cartridge (58) adapted to receive the product, a closure cap (20), a cartridge case (76), and a plunger mechanism. The closure cap (20) is adapted to retain an elastomeric disc seal (52) during lyophilization and includes diametrically opposed ledges (38, 40). The closure cap (20) and seal (52) are adapted to cover a neck portion of the ampule (58), the neck portion having on its end a radially extending circumferential flange (62). The ledges (38, 40) of the closure cap (20) and the flange (62) of the neck portion allow the closure cap (20) to remain open during lyophilization, oxygen purge and nitrogen overlay. An oval-shaped indentation formed on the inside of the closure cap (20) aids in snapping the closure cap (20) about the flange (62) without crimping to retain the closure cap (20) underneath the flange (62). Reconstitution of the lyophilized drug is accomplished without foaming by use of an obliquely angled connector (30) which causes the diluent to indirectly impinge on the drug. The injection pen (104) and cartridge assembly (90) cooperate such that the length of travel of the plunger rod (108) during retraction is less than the axial length of a recess (107) in the rod tip (73).



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CARTRIDGE ASSEMBLY FOR A LYOPHILIZED COMPOUND FORMING A DISPOSABLE PORTION OF AN INJECTOR PEN AND METHOD FOR SAME

The present invention relates to the sealing and dispensing of pharmaceuticals and, more particularly to the sealing and dispensing of a lyophilized drug in a cartridge assembly.

In current technology, drugs or compounds manufactured for various injections are generally encapsulated in sterile glass cartridges. The glass cartridges characteristically have a sealed end with the other end of the cartridge generally having a restricted opening in the form of a neck having a circumferential flange. The opening can be closed off with a rubber membrane held into place with an aluminum seal crimped therearound. Where the drug or compound is to be later dispensed either directly from the cartridge or in a dispensing device such as a pen dispenser, the cartridge includes at the end opposite the restricted opening, an open end generally having a rubber plunger closing the open end. The rubber plunger also acts as a piston to force the drug or compound contained within the cartridge out of the restricted opening into which there has generally been inserted a cannula, by action of a plunger rod exerting axial pressure upon the rubber plunger.

Cartridges for use with dispenser devices or pens as described above are generally known in the prior art. U.S. Patent 4,936,833 Sams, shows a typical glass cartridge having an open end with a plunger therein, and an opposite end including a restricted opening sealed with a rubber membrane and crimped metal collar. The cartridge is insertable into a housing forming a part of a dispenser pen, with a cap for receiving a two ended cannula. Typical of these device are U.S. Patent 4,883,472 Michel, and U.S. Patent 4,973,318 Holm et al.

Lyophilized drugs or compounds are currently being utilized as the basis for injectionable compounds, such as

human growth hormone (HGH), insulin, and the like. Lyophilization is the rapid freezing of a material at a very low temperature followed by rapid dehydration by sublimination in a high vacuum. The lyophilized compound is generally contained in a glass vial or cartridge. However, the process described above is not suitable for lyophilized compounds which are moisture and oxygen sensitive. When the moisture is removed from the compound during lyophilization, the oxygen in the glass cartridge containing a lyophilized drug must be replaced with nitrogen after the lyophilization process. This step of replacing the oxygen with nitrogen is termed nitrogen overlay and is accomplished within the lyophilizing chamber (freeze dryer).

One technique is to lyophilize the drugs or compounds in rubber stoppered glass vials. During lyophilization of the compounds in the glass vials, the rubber stopper used to close the vial is partially seated in the neck of the vial. The moisture which is removed from the compound during lyophilization is vented out through grooves or slots formed in the rubber stopper. As a general method of closing the vials, the shelves of the lyophilization chamber vertically move together to press the rubber stopper down into the vial, until the vents in the stopper are well inside the neck opening of the vial. An aluminum seal is then crimped about a flange on the neck of the vial.

The use of aluminum as a crimping seal for the rubber stopper is not, however, preferred due to the possibility of aluminum dust or particles contaminating the compound during the initial crimping, reconstitution, or administration processes. In addition, such processes as above are not well suited for efficient lyophilization.

Thus, it is desired to eliminate the aluminum crimping seal as well as provide an easier method of assuredly allowing lyophilization of a compound and sealing the same.

In order to administer a lyophilized compound, it is necessary to reconstitute the compound prior to administration with a suitable diluent. Reconstitution is accomplished by using a syringe with a needle to withdraw the diluent from a separate vial and inject it into the vial containing the lyophilized compound. The vial containing the lyophilized compound is placed in a holder during reconstitution. Because the cartridge is filled with the lyophilized compound and nitrogen, addition of the diluent produces extra pressure within the cartridge which creates the possibility of forcing the plunger out of the cartridge. Having the plunger forced out of the cartridge during reconstitution would undesirably result in a total loss of the compound.

During reconstitution, the diluent injected from the syringe into the cartridge directly impinges upon the lyophilized compound which causes the lyophilized compound to foam. The foam undesirably creates extra head space within the cartridge such that the proper amount of diluent is not mixed with the compound, resulting in an improper diluent to compound ratio. In order to alleviate this, one must wait for the foam to subside.

A patient needle is then attached to the disc sealed end of the cartridge which thus allows the compound to be injected. Current injector pens dispense a selectable amount of drug depending on the required dosage. A plunger mechanism, including a plunger rod, pushes against the plunger in the cartridge. After each injection, the plunger mechanism and plunger rod retract during a resetting function of the injector pen. However, complete disengagement of the plunger rod from the plunger mechanism during retraction is highly undesirable, and can render the injector pen inoperative.

Because of the expanding use of pen dispensers or injectors utilizing cartridges for the administration of injectionable compounds, it is desired to provide a

lyophilized compound in an improved cartridge suitable for use in an injector pen.

The present invention, in one form thereof, provides a method of lyophilizing a compound in a glass cartridge and sealing the same utilizing a closure cap with a seal, and encapsulating the same into a cartridge assembly.

A method of lyophilizing and sealing an injectionable product within a cartridge is provided which includes, providing a cartridge having a neck defining a first opening therein, and a second opening therein distal the first opening, the neck including a circumferential radially outwardly extending flange adjacent the first opening, inserting a plunger in the second opening, and inserting the product to be lyophilized into the cartridge. Further, there is provided a cap having a cylindrical portion and a seal, the cylindrical portion including an open bottom receivable over the neck, the cap including a top having an opening therein for receipt of a needle therethrough, at least one vent circumferentially disposed in the cap, and a deformable ledge in the cap extending radially inwardly from the cylindrical portion axially below the vent, the seal being axially disposed between the vent and the top so as to block the top opening. The cap is then placed onto the neck such that the deformable ledge rests upon the neck flange and the vent is in communication with the neck opening, after which the cartridge with the cap is placed in a lyophilizing chamber, wherein the product is lyophilized, and the cap is closed by exerting a downward pressure upon the cap such that the deformable ledge yieldably snaps around the neck flange to be lockingly retained thereunder, the vent is closed from communication with the neck opening, and the seal is compressed into sealing engagement with the neck opening by downward pressure exerted by the top thereby providing an air impermeable barrier between the top opening and the neck opening.

The method of sealing a lyophilized product within a cartridge is further characterized by providing a sleeve having a first open end and a radially inwardly extending circumferential ledge into which the cartridge is placed. The cartridge is axially seated against the ledge and the sleeve is permanently attached to the cap.

A plunger rod tip having a plunger head is received in the sleeve between the plunger and ledge such that the plunger head is axially adjacent the plunger.

The present invention, in one form thereof, provides a cartridge assembly containing a lyophilized drug having a cartridge, a cap and seal, a cartridge sleeve, and a plunger mechanism forming a disposable portion of an injector pen.

A cartridge assembly for holding a lyophilized drug and forming a disposable part of an injection pen comprises a cartridge having a plug in one end and a neck on another end, the cartridge including a circumferentially extending flange about the neck, the neck defining an opening therein, a cap disposed about the neck, the cap having a first cylindrical portion including an open bottom received over the neck, a top having an opening therein for receipt of a needle therethrough, and a deformable ledge extending radially inwardly from the first cylindrical portion and lockingly retained under the neck flange. A resilient seal is disposed in the cap between the neck opening and the top opening forming an impermeable barrier therebetween, with a sleeve radially disposed about and permanently attached to the cartridge.

Further, the sleeve is permanently attached to the cap, and includes a first cylindrical portion adapted to receive the cartridge and a second cylindrical portion axially below the first cylindrical portion and concentric therewith, and a radially inward circumferentially extending ledge defined at the junction of the first and second cylinder for axially retaining the one end of the cartridge.

In one form thereof the present invention provides a method and apparatus for reconstituting a lyophilized compound, the lyophilized compound contained within an interior space defined by an inner wall of the cartridge having an inlet at one end thereof. The method comprising the step of injecting a diluent into the cartridge via the inlet such that the diluent impinges on and runs down the inner wall of the cartridge to thereby contact the compound, whereby foaming of the compound is alleviated.

A connector is releasably secured to the inlet end of the cartridge and adapted to receive and hold a syringe containing a diluent. The connector has a first portion defining a longitudinal axis which forms an oblique angle with the longitudinal axis of the cartridge. The syringe is supported by the connector at the oblique angle whereby the diluent is injected into the cartridge via the inlet at the oblique angle so that the diluent impinges on the wall of the cartridge.

The cartridge of the present invention is adapted to be used with an injector pen apparatus for administering a drug. The apparatus comprises a cartridge assembly having a cartridge with a movable plunger therein and an inlet on one end thereof. The cartridge assembly includes a rod tip having a recess therein and disposed axially adjacent the plunger and is adapted to exert pressure upon the plunger for dispensing the drug from the cartridge. An injector pen is releasably engaged with the cartridge assembly, the pen including a movable rod adapted to engage the recess of the rod tip in order to move the rod tip during dispensing of the drug. For injection of the drug, the rod retracts a known distance away from the plunger within the recess of the rod tip. The rod is then advanced towards the plunger a selected number of discrete increments as determined by the number of clicks depending on the desired dosage to be administered. During injection, the rod then advances the known distance towards the plunger which causes the plunger to advance.

the distance determined by the amount of discrete increments. The rod then retracts the known distance within the travel length of the rod tip.

It is an advantage of the present invention that the closure cap does not require close tolerances in cartridge manufacture.

It is another advantage of the present invention in that the cartridge, closure cap with seal, and cartridge case with plunger form a tamper resistant package.

It is yet another advantage of the present invention that the cartridge assembly prevents the plunger from outwardly moving during shipment of the cartridge assembly and during reconstitution of the lyophilized drug contained therein.

It is further an advantage of the present invention that foaming of the lyophilized compound is prevented during reconstitution thereof.

It is still another advantage of the present invention in that the cartridge assembly is protected from breakage.

It is also an advantage of the present invention that container integrity for the drug is increased.

The above mentioned and other features and objects of this invention, and the manner of attaining them, will become more apparent and the invention itself will be better understood by reference to the following description of embodiments of the invention taken in conjunction with the accompanying drawings, wherein:

Fig. 1A is a perspective view of the closure cap according to an aspect of the present invention;

Fig. 1B is a bottom view of the closure cap taken along line 1B-1B of Fig. 2;

Fig. 2 is a sectional elevational view of the closure cap taken along line 2-2 of Fig. 1A;

Fig. 3 is an elevational cutaway view of the glass cartridge and plunger;

Fig. 4 is an elevational cutaway view of the glass cartridge with plunger seated on a shelf with the closure cap in an open condition;

Fig. 5 is an elevational cutaway view of the glass cartridge with plunger seated on a shelf with the closure cap in a closed position;

Fig. 6 is an elevational cutaway view of a cartridge assembly with user needle and cap;

Fig. 7 is an elevational cutaway view of the cartridge assembly according to an embodiment of the present invention;

Fig. 8 is a partial cutaway view of the cartridge assembly according to an embodiment of the present invention installed on a dispensing pen unit;

Fig. 9 is an elevational cutaway view of the cartridge assembly during reconstitution;

Fig. 10 is an elevational cutaway view of the cartridge assembly with connector and connector lid before insertion into a dispensing pen and reconstitution;

Fig. 11 is a partial cutaway view of the cartridge assembly installed on a dispensing pen; and

Figs. 12-14 are partial cutaway views of the plunger and rod mechanism as utilized with the dispensing pen illustrating the injection process.

Corresponding reference characters indicate corresponding parts throughout the several views. The exemplifications set out herein illustrate a preferred embodiment of the invention, in one form thereof, and such exemplifications are not to be construed as limiting the scope of the invention in any manner.

Referring now to Figs. 1A, 1B, and 2, there is shown a closure or lyophilization cap 20 in accordance with an aspect of the present invention. In general, cap 20 is preferably made of an injection molded plastic, although other suitable materials as known in the art may be utilized with the cap thus fabricated accordingly. Cap 20 has a cylindrical bottom portion or skirt 22 of a given

axial length and inner radius sufficient to extend about at least a portion of a lyophilization cartridge. As further described hereinbelow, bottom portion or skirt 22 stabilizes cap 20 when placed onto cartridge 58 in the open position during lyophilization, and serves as a guide during closing of the cap. Cylindrical bottom portion 22 has a slightly upwardly and inwardly sloping annular shoulder 24, with a cylindrical top portion or neck 26 disposed axially above and inwardly concentric to cylindrical bottom portion 22. Top portion 26 includes threads 28 circumferentially formed on the outer upper periphery thereof which are adapted to threadedly receive a connector 30 (Figs. 9 and 10) and needle assembly 32 (Fig. 6) both of which are described in more detail hereinbelow. Formed in cylindrical top portion 26 below threads 28 are two diametrically opposed circumferentially extending rectangular openings 34 and 36 which serve to vent moisture from cartridge 58 (Figs. 3-5) during lyophilization and which allow the oxygen purge and nitrogen overlay process to occur thereafter.

As best seen in Fig. 1B, extending radially inward from wall 33 and 35 just below openings 34 and 36 are two ledges 38 and 40 having a circumferential length roughly corresponding to openings 34 and 36. As will be described in more detail hereinbelow, ledges 34 and 36 serve the dual function of allowing closure cap 20 to be seated upon cartridge 58 thus permitting communication between openings 34, 36 and the interior 60 of cartridge 58, and of snapping around and under circumferential flange 62 of cartridge neck 64 upon closing cap 20. Ledges 38 and 40 are sized and shaped so as to reduce the closing pressure required during the closing process, described hereinbelow, and to minimize the amount of cap deformation as closure is taking place. Cap 20 includes a top 41 which downwardly slopes from the outer upper edge of cylindrical top portion 26 terminating at an aperture 46 adapted to expose a seal 52 and receive a needle as

described in detail hereinbelow. Two arched slots 42 and 44 are disposed in top portion 41 each axially upwardly of a respective side opening 34, 36. Arched slots 42 and 44 are formed during the molding process in order to achieve the undercut ledges 38 and 40 sufficiently large enough to allow for variations in the diameters of cartridge flanges.

Defined at the level 50 of ledges 38, 40 interior to cap 20 are walls 33, 35, 47, and 48 that define an oval or elliptic surface 49 whose major axis is transverse to an axis defined by connecting the middle of side openings 34, 36 or ledges 38, 40 such that each longitudinal end of oval or ellipse 49 is located 90° from each ledge 38 and 40. Walls 47 and 48 are thinner than walls 33 and 35 carrying ledge 38 and 40 so that as the ledges are forced outwardly during seating of cap 20, walls 47, 48 can move inward to accommodate such outward movement of walls 33 and 35 carrying ledges 38, 40. However, the thicker walls 33, 35 provide adequate support for ledges 38, 40 to prevent dislodgement of cap 20 from cartridge 58. This reduces the pressure required to close cap 20 onto cartridge 58 after lyophilization and nitrogen purge in order to prevent stress fractures in cap 20 and allow for more cartridges to be closed at one time. Such elliptical configuration of walls 33, 35, 47 and 48 extends the entire inner axial length thereof.

A circumferential ridge 51 is disposed about the interior of cylindrical top portion 26 axially below and adjacent top 41. Ridge 51 permits seal 52, such as for instance a laminated, two-piece rubber seal, to be seated therein without dislodging for efficient covering of opening 46.

The structure of cap 20 assists the natural deformation that occurs during the closure process. Thus, as cap 20 is pressed onto cartridge 58, ledges 38, 40 spring outward to allow it to go over and then underneath neck flange 62 (see Fig. 3).

What has thus been described hereinabove is a cap adapted to be seated upon a cartridge during lyophilization and which effectively and positively closes upon the cartridge to securely hold a disc seal about the opening. The cap is designed for efficient lyophilization and optimal nitrogen sealability while requiring only a minimum amount of closure force.

The process of lyophilizing a compound in cartridge 58 utilizing the hereinabove described cap 20 will now be described in conjunction with Figs. 3-5. First, it should be noted that the various parts are sterilized prior to placement in the freeze dryer so that the compound to be lyophilized will be free from contamination. Secondly, it should be noted that a plurality of cartridges (up to 6000 or more) are generally lyophilized at one time. The cartridges are held in blocks defining a matrix of rows and columns of cartridges with the blocks placed in a freeze dryer chamber between movable shelve units, described hereinbelow. A typical configuration is 2000 per layer with three layers. The general structure of the various elements will also be described when introduced during the description of the process.

Cartridge 58 is manufactured of glass and consists of a tube portion 59 defining an inner chamber 60 and which openly terminates at one end with a circumferential inwardly bulbous lip 56. The other end of tube 59 includes an upwardly and inwardly sloping shoulder portion 66, a reduced diameter neck 64 and a rim 63 having circumferential flange 62 having a circumferential radius greater than that of neck 64. The end of cartridge 58 including flange 62 defines an opening 68 which communicates with inner chamber 60. Recessed neck 64 has a diameter that is smaller than shoulder 66. A rubber plunger 54 having knobs 55 is first disposed in the end having lip 56 just far enough into cartridge 58 such that the end of plunger 54 is adjacent lip 56. This is to keep the inside of cartridge 58 sterile after lyophilization.

Cartridge 58 with plunger 54 is placed between shelves 72 and 74 in the freeze dryer (not shown) with the liquid compound or drug 70 to be lyophilized contained therein. Cap 20 having rubber disc seal 52 disposed therein is placed over flange 62 defining a first or open position, the placement of cap 20 onto cartridge 58 occurring either before placement of cartridge 58 into the freeze dryer or thereafter. However, compound 70 is placed into cartridge 58 before the placement of cap 20 upon flange 62. Seal 52 is preferably a laminate of two different materials, the upper material 52a being a good sealing material, with the bottom material 52b being a good product contact material such as, for example, a normal butyl rubber compound. However, any resilient sealing material may be utilized which provides a good product contact material on the bottom and a good sealing material on the top.

Referring specifically to Fig. 4, cap 20 is designed such that ledges 38 and 40 rest on top of flange 62. In the first or open position a part of cylindrical bottom portion 22 circumferentially surrounds an upper part of tube 59 thereby serving as a stabilizer for cap 20 and a guide when cap 20 is moved to the second or closed position. Seal 52 is held in an elevated position above cartridge opening 68, while side openings 34 and 36 are above opening 68 thus allowing communication between the ambient atmosphere and inner chamber 60 of cartridge 58. At this point lyophilization begins.

Lyophilization, or freeze drying, which is represented in Fig. 4 as an upward and outward arrow, purges the moisture from compound 70 such that a waterless compound is left. Although the arrow is shown exiting only one side opening 36, it should be understood that the moisture is vented out through both openings 34, 36 during lyophilization. Once the moisture has been vented out of cartridge 58, oxygen is purged from the lyophilization chamber and thus cartridge 58. A nitrogen overlay process

is then initiated. The nitrogen overlay process is represented in Fig. 4 as an inward and downward arrow entering from side opening 34, but as is the case for the venting of moisture and oxygen purge, the nitrogen enters through both side openings 34 and 36 to fill the entire inner space 60 of cartridge 58 not occupied by the now lyophilized compound 70. The nitrogen overlay process is used where the lyophilized compound is oxygen sensitive, as, for example, HGH.

At this point and referring now to Fig. 5, shelves 72 and 74 move vertically together in order to close cap 20 onto neck 64. As described above, cap 20 includes an oval or elliptical indentation 47 and inner wall 48 which allows cap 20 and ledges 38 and 40 to deform and flex so that ledges 38 and 40 snap around flange 62 as cap 20 is downwardly pressed by the pressure exerted by closing shelves 72 and 74. A force of only about 10-12 lbs. is thus necessary to effect closure of cap 20 about neck 64 and neck flange 62. Once in place, cylindrical bottom portion 22 extends about an upper part of tube 59, while ledges 38 and 40 prohibits removal of cap 20 by extending under neck flange 62 between the flange and sloped shoulder section 66.

Upon closure of cap 20, seal 52 is compressed between the top of rim and downwardly sloped cap top 41 to effect a positive, airtight seal between the ambient atmosphere and the nitrogen and lyophilized compound within cartridge 58. There is no need for a crimp seal, while both the lyophilization and closure processes are completed within the lyophilizing chamber. At this point, the sealed cartridge may be removed from the lyophilizing chamber. A cake or plug of compound 70 is thus sealed within a nitrogen filled cartridge.

After lyophilization, and referring to Fig. 7, sealed cartridge 58 is then placed into a cartridge sleeve, barrel, or retainer 76 through an opening 77 in one end thereof. The sleeve is preferably made from a suitable

plastic or other material which provides protection for the glass cartridge.

Sleeve 76 comprises a first tubular portion 78 having an inner diameter 79 of sufficient size such that a segment of first tubular portion 78 radially surrounds or overlaps cylindrical bottom portion 22 of cap 20. At this junction, sleeve 76 is attached or sealed to cap 20 by use of a solvent, adhesive bond, snap fit, sonic weld, or the like, such that cartridge 58 is retainingly held in sleeve 76. Sleeve 76 also includes a second tubular portion 80 having a smaller diameter than first tubular portion 78 such that tube 59 of cartridge 58 is inwardly circumjacent the inner diameter thereof. Threads 86 on the outer periphery of second tubular portion 80 permit sleeve 76 to be received onto an injection pen device.

Sleeve 76 further comprises a third tubular portion 82 having a smaller diameter than second tubular portion 80, the second tubular portion defining an annular stop or ledge 84 at the junction of second and third tubular portions 80 and 82. Stop 84 supports lip 56 such that tube 59 is supported thereon. A sleeve cap 88 optionally may fit about the top of the cartridge assembly 90 to further protect the seal assembly. Thus, the cartridge is securely held by and contained within sleeve 76 and ready for reconstitution before administration and placement into an injector pen dispenser.

Sleeve 76 has a smaller diameter opening 69 at the other end through which extends a plunger rod tip 71. Rod tip 71 is placed within sleeve 76 before insertion of cartridge 58, and has a circular rod head 73, slightly less than the inner diameter of cartridge 58, on one end of a hollow cylindrical body 85. The lower portion of rod head 73 is seated against sleeve ledge 84 and is of sufficient diameter such that rod tip 71 is retained in sleeve 76. Rod tip body 85 is of sufficient length to axially extend from head 73 to the axial end of third tubular portion 82. Cylindrical body 85 defines an

axially elongated cylindrical recess or bore 107. Recess 107 defined by cylindrical body 85 between bottom portion 81 of rod head 73 and end portion 83 is of a specific axial length, for example, eight and nine tenths millimeters (8.9 mm). The upper surface of circular rod head 73 of rod tip 71 abuts plunger 54 and includes an annular groove 75 into which knobs 55 of plunger 54 are seated. As pressure is applied to plunger 54 in order to administer the reconstituted compound, plunger 54, being an elastomeric or rubber, has a tendency to deform during compression. However, because of its resiliency, plunger 54 returns to its original shape, which sequence could cause weeping of the liquid from around the plunger. Rod head 73 serves to distribute the load exerted by the compression of rod tip 71 in order to eliminate weeping from about plunger 54 which could occur as a result of uneven or localized compression of plunger 54. Annular groove 75 retains knobs 55 to prevent lateral deformation, which could cause weeping.

As shown in Fig. 10, a connector 30 is threadedly attached to threads 28 of cap 20. This occurs after placement of cartridge 58 in sleeve 76 and attachment of cap 20 thereto. Connector 30, introduced hereinabove, is threadedly attached to threads 28 of cap 20 and includes an angled first section 92 and a larger diameter second section 94. First section 92 is tubular in shape and includes an upper section 111 and, at its lower end, an angled neck portion 113 having mating threads for threads 28. Neck portion 113 is essentially concentric and defines a common axis with cartridge 58. Upper section 111 defines an axis which thus forms an oblique angle with the axis of neck portion 113. Larger diameter portion 94 is eccentric with upper section 111 of first section 92. A common axis is also defined between upper section 111 and portion 94.

A lid 95 is snapped in place over cylindrical second section 94 thereby sealing the space there between. This

entire assembly is then sterilized so that the contents of the cartridge and the area about the disc seal is sterile for later reconstitution and administration.

Reconstitution is performed as shown in Fig. 9. After removal of connector lid 95, connector 30 is thus adapted to receive a syringe 96 in second section 94 which supports syringe 96 but allows needle 98 to enter hole 46 and penetrate seal 52 such that only a small section of needle 98 extends into cartridge 58. During reconstitution, the action produced by the force of moving diluent upon the lyophilized cake (e.g. HGH) triggers a reaction which causes the HGH cake to become agitated and foam. Foaming undesirably creates air bubbles, thereby limiting the amount of diluent that can be added to the cartridge. This can result in improper dilution ratios of the lyophilized compound. Furthermore, once the foam subsides, too large a headspace is created within the cartridge.

According to one aspect of the present invention, connector 30 is obliquely angled as described above such that needle 98 is oriented toward and preferably in close proximity to wall 58 and injects diluent 102 down the side of the interior wall of cartridge 58 in order to prevent foaming of the compound during the reconstitution process. Side impingement of the diluent reduces the velocity of the diluent as it travels toward and onto the HGH cake. This indirect administration of the diluent by causing the diluent to impinge on the inner side wall of cartridge 58 and then run down around and into the HGH prevents foaming.

Syringe 96 is prefilled with a suitable diluent 102, and as plunger 100 of syringe 96 forces fluid into the lyophilized cartridge, the nitrogen in cartridge 58 is compressed. Releasing syringe plunger rod 100 while holding the syringe above the cartridge, allows the pressure in the cartridge to equilibrate by venting the nitrogen into the syringe, leaving the diluent in the

cartridge to mix with the lyophilized drug. The syringe is then removed and discarded.

A transfer needle 32, such as those manufactured by Becton-Dickinson, can then be threadedly attached to cap 20 where connector 30 was attached during reconstitution. This is shown in Fig. 6. The typical transfer needle 32 is a double-ended needle 110, which extends in one direction through hole 46 in top 41 and seal 52 to communicate with the reconstituted drug within the cartridge. Needle 110 is secured in a needle housing 112 and protected during nonuse by a plastic cap 114 and needle assembly protector cap 116.

Referring in particular now to Fig. 8, cartridge assembly 90 is threadedly attached to an injector pen 104, such as that manufactured by Disetronic AB of Burgdorf, Switzerland. A plunger rod 108 fits into recess 107 of rod tip 71 in order to effect ejection of the reconstituted drug from the cartridge. The inside length of rod tip 71 is adapted to retain the injector pen plunger rod 108 during the injector pen's compression and retraction stroke. When the drug is to be administered to the patient, the needle assembly 32 as shown in Fig. 6 is attached to cap 20 as described hereinabove.

One such type of injector pen is shown in Fig. 11 and its operation described in conjunction with additional Figs. 12-14. Referring to Fig. 11, cartridge assembly 90 is shown connected to injector pen 104 via complementary threads 86, 101. Injector pen 104 includes a pen rod 108, a dose knob 118 and a release button 120. Pen rod 108 fits into a suitable mechanism within pen body 106 for providing the injector function as described below in conjunction with Figs. 12-14.

It should be noted with respect to Figs. 12-14 that for simplicity of discussion and understanding of an aspect of the present invention that only rubber plunger 54 and plunger rod tip 71 of the cartridge assembly are shown in relationship to pen 104 and, in particular pen

rod 108. To load the assembly for the first time, release button 120 is pushed such that dose knob 118 pops out. At this point, pen rod 108 retracts a known, or predetermined distance, for example 8.1 millimeters away from plunger 54 within recess 107. Dose knob 118 is then turned until dose knob 118 stops which causes pen rod 108 to travel forward towards plunger 54 a set maximum amount for purging. Upon retraction, pen rod 108 cooperates with rod tip 71 in that pen rod 108 does not travel any more than 8.1 millimeters out of the 8.9 mm (for example) recess 107 of the rod tip 71. End 109 of plunger rod 108 thus never retracts past a plane defined at the end 83 of rod tip 71 perpendicular to an axis of elongation of rod tip 71. Thus, rod 108 never disengages from recess 107.

The rod tip, being an integral part of the housing for the cartridge assembly prevents the plunger 54 in the cartridge from being forced out during the reconstitution process. Further, rod tip 71 allows movement required by the pen's plunger rod 108 during dose setting and injection. When dose knob 118 is pushed in, the unit purges 95 percent of all of the air in the cartridge in order to obtain a proper head space. Thus, after reconstitution, and initial purging, the injector pen assembly is ready for the administration process as shown in Fig. 11.

In order to administer the drug to the patient, release button 120 is pressed which causes dose knob 118 to pop out and correspondingly cause pen rod 108 to retract the 8.1 mm maximum travel distance within the 8.9 mm rod tip 71, each action being depicted by respective arrows in Fig. 12. As noted hereinabove, end 109 never retracts past end 83. Dose knob 118 is then turned through so many clicks, the clicks corresponding to volume units of dosage depending on the required amount of dosage. Each click corresponding to a given volume of injectionable liquid. This is depicted in Fig. 13. As the required number of clicks are set via dose knob 118,

pen rod 108 correspondingly moves forward an amount equal to the number of clicks, with each click correspondingly moving pen rod 108 a predetermined distance being coordinated with a set dosage amount.

As shown in Fig. 14, when dose knob 118 is depressed, pen rod 108 thus contacts rod head 73 of rod tip 71 to administer the drug by traveling the 8.1 mm distance. Upon retraction of pen rod 108 in order to administer another dose, pen rod 108 retracts the set 8.1 mm distance within the 8.9 mm recess 107. This ensures that pen rod 108 never comes out of rod tip 107.

The process as depicted in Figs. 12-14 is repeated at the prescribed times until all of the drug has been administered. A dose indication device 122 is provided to visually indicate the dosage set by dose knob 118. Such dose indication may be purely mechanical in nature or electronic, such as an LCD display.

Once the entire drug has been administered to the patient, the entire cartridge assembly and patient needle assembly is then discarded. The injector pen is then ready for another cartridge assembly 90.

While this invention has been described as having a preferred design, the present invention can be further modified within the spirit and scope of this disclosure. This application is therefore intended to cover any variations, uses, or adaptations of the invention using its general principles. Further, this application is intended to cover such departures from the present disclosure as come within known or customary practice in the art to which this invention pertains and which fall within the limits of the appended claims.

CLAIMS

1. A method of lyophilizing and sealing an injectionable product within a cartridge, the method comprising the steps of: providing an elongate cartridge (58) having on a first end thereof a shoulder (66), a rim (63) defining a first opening and having a circumferential radially outwardly extending flange (62) adjacent said first opening, and a neck (64) disposed axially between said flange and shoulder, said neck having a diameter smaller than said flange and shoulder, said cartridge including a second opening on a second end thereof distal said first opening; and inserting a plunger (54) in said second opening; characterized by:

providing a cap (20) having a cylindrical portion and a seal (52), said cylindrical portion including an open bottom receivable over said neck, said cap including a top having an opening therein for receipt of a needle therethrough, at least one vent (34) circumferentially disposed in said cap, and at least two deformable ledges (38,40) on said cap extending radially inwardly from said cylindrical portion axially below said vent, said seal being axially disposed between said vent and said top so as to block said top opening;

inserting the product to be lyophilized into said cartridge (58);

placing said cap onto said cartridge such that said deformable ledges (38,40) rest upon said flange (62) and said vent is in fluid communication with said cartridge first opening; placing said cartridge with said cap in a lyophilizing chamber; lyophilizing the product; and

closing said cap by exerting a downward pressure upon said cap such that said deformable ledges yieldably snap around said flange (62) and into said neck to be lockingly retained therein, said vent (34) is blocked from communication with said cartridge first opening, and said seal (52) is pressed into sealing engagement with said rim (63) by downward pressure exerted by said top thereby

providing an air impermeable barrier between said top opening and said cartridge first opening.

2. The method of claim 1, characterized in that the step of closing said cap (20) is preceded by the steps of purging oxygen from said cartridge (58) and providing a nitrogen overlay in said cartridge.

3. The method of claim 1, further characterized by: providing a sleeve (78) having a first open end for receiving said cartridge (58) and a radially inwardly extending stop (84); and placing said cartridge into said first open end of said sleeve such that said cartridge is positively axially retained in said sleeve against said stop.

4. The method of claim 3, characterized by the subsequent step of permanently attaching said sleeve (78) to said cap (20).

5. The method of claim 3, characterized in that said sleeve (78) includes a second open end distal said first open end and axially below said sleeve stop, and the step of placing said cartridge into said sleeve is preceded by the step of inserting a plunger rod tip (71) having a head (73) in said sleeve such that said plunger rod tip extends from said second opening and said head is axially adjacent said plunger (54).

6. The method of claim 5, further characterized by the step of capturing said head (73) between said sleeve ledge (84) and said plunger (54).

7. The method of claim 1, characterized in that the step of placing the cartridge (58) in a lyophilizing chamber includes supporting said cartridge on a first surface (74), and the step of closing said cap includes exerting a downward pressure upon said cap (20) by contact of a second surface (72) upon said cap induced by relative vertical movement between said first and second surfaces.

8. A cartridge assembly for holding a lyophilized drug and forming a disposable part of an injection pen, the cartridge assembly comprising:

an elongate cartridge (58) having on a first end thereof a shoulder (66), and a rim (63) defining a first opening and having a circumferential radially outwardly extending flange (62) adjacent said first opening and a neck (64) disposed axially between said flange and shoulder, said neck having a diameter smaller than said flange and shoulder, said cartridge including a second opening on a second end thereof distal said first opening;

a cap (20) disposed on said first end of said cartridge, said cap having a first cylindrical portion including an open bottom received over said first end, a top having an opening therein for receipt of a needle therethrough, and at least two elastically deformable ledges (38,40) extending radially inwardly from said first cylindrical portion and lockingly retained under said neck flange;

a resilient seal (52) in said cap disposed between said first opening and said top opening and forming an impermeable barrier therebetween a vent opening in said cap below said seal; a sleeve (78) radially disposed about and permanently attached to said cap; and

a plunger rod tip (71) slidably disposed in said sleeve, said plunger rod tip including a head (73) axially adjacent said plunger for exerting pressure against said plunger during administration of the drug.

9. The cartridge assembly of claim 8, characterized in that said sleeve (78) includes a first cylindrical portion adapted to receive said cartridge and a second cylindrical portion axially below said first cylindrical portion and concentric therewith, and a radially inward circumferentially extending ledge (84) defined at the junction of said first and second cylinder for axially retaining said one end of said cartridge.

10. The cartridge assembly of claim 8, characterized in that said rim (63) of said cartridge outwardly tapers for compressingly sealing said resilient seal (52) between said cartridge and said cap.

11. The cartridge assembly of claim 8, characterized in that said cap (20) includes an oval shaped wall carrying said ledges (38,40) wherein said wall is thinner along the major axis of the oval than along the minor axis of the oval, and said ledges are disposed generally on the minor axis of the oval.

12. The cap and cartridge assembly of claim 8, characterized in that said deformable ledge comprises two circumferential and inwardly extending ledges (38,40) separated by two arcuate portions of an oval-shaped wall (50) and said ledges are located on the minor axis of said oval-shaped wall.

13. The cap and cartridge assembly of claim 12, characterized in that said oval-shaped wall (50) is thinner along the major axis of the oval than along the minor axis of the oval.

14. A method reconstituting a lyophilized compound, the lyophilized compound contained within an interior space defined by an inner wall of a cartridge (59) having an inlet at one end thereof, the method comprising the steps of: attaching a connector (30) to the inlet end of the cartridge, the connector having an interior space and defining an axis along a longitudinal length thereof, the axis of the connector forming an oblique angle relative to the axis of the cartridge; placing a syringe (96) having a needle (98) and containing the diluent into the interior space of the connector, such that the needle (98) is oriented obliquely toward the inner wall of the cartridge; and injecting a diluent from the syringe into the cartridge via the inlet such that the diluent impinges on and runs down the inner wall of the cartridge before contacting the compound (70) whereby foaming of the compound is prevented.

15. An apparatus for reconstituting a lyophilized drug contained within an inner space of a cartridge, the cartridge (59) having an inlet on one end thereof, and defining a longitudinal axis extending through the inlet,

the apparatus comprising: a connector (30) releasably secured to the inlet end of the cartridge and adapted to receive and hold a syringe (96) containing a diluent, the connector having a first portion (111) defining a longitudinal axis which forms an oblique angle with the longitudinal axis of the cartridge, the syringe being supported by the connector at the oblique angle whereby the diluent is injected into the cartridge via the inlet at the oblique angle.

16. The apparatus of claim 15, characterized in that said connector (30) is received on the inlet end of the cartridge, the connector further including a second portion (113) eccentric with said first portion, said second portion having a larger diameter than a diameter of said first portion and adapted to retain and support the syringe.

17. An injector pen and cartridge apparatus for administering a drug, the apparatus comprising: a cartridge assembly (90) having a cartridge with a movable plunger (54) therein and an inlet on one end thereof, said cartridge assembly including a rod tip (71) disposed axially adjacent said plunger and adapted to exert pressure upon said plunger for dispensing the drug from said cartridge, said rod tip including a recess (107) of a given axial length therein; and an injector pen releasably engaged with said cartridge assembly, said pen including a movable rod (108) received in said recess (107) and engaging said rod tip in order to advance said rod tip during dispensing of the drug; characterized in that said movable rod (108) has a retraction travel length that is less than the axial length of said recess whereby said movable rod remains engaged with said rod tip.

18. The cartridge assembly of Claim 17 characterized in that said plunger rod tip (73) is captured by said ledge (84) of said sleeve to thereby retain said plunger rod tip in said sleeve.

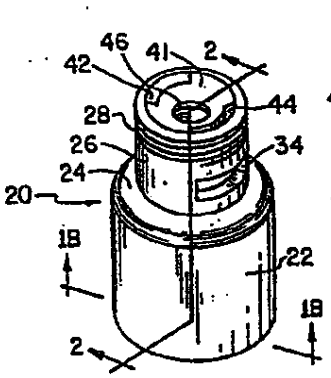

FIG. 1A

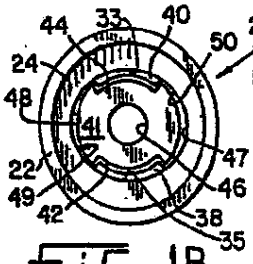

FIG. 1B

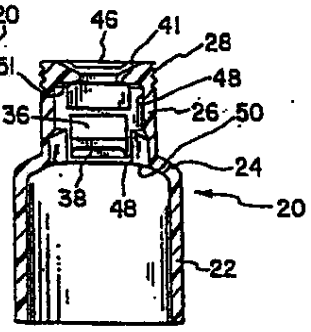

FIG. 2

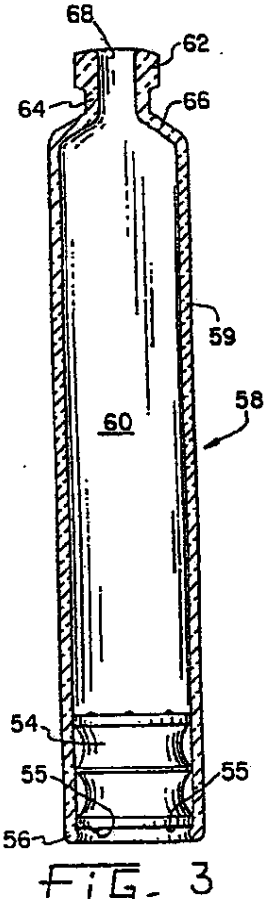

FIG. 3

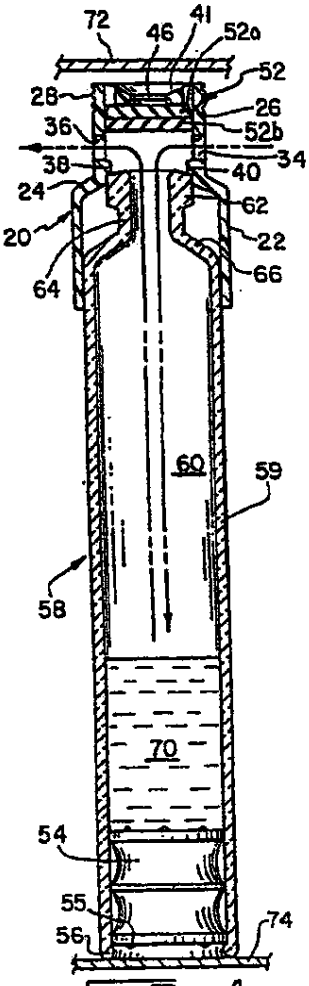

FIG. 4

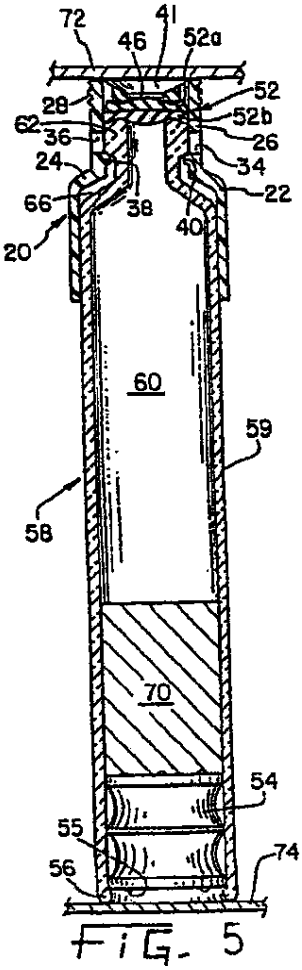

FIG. 5

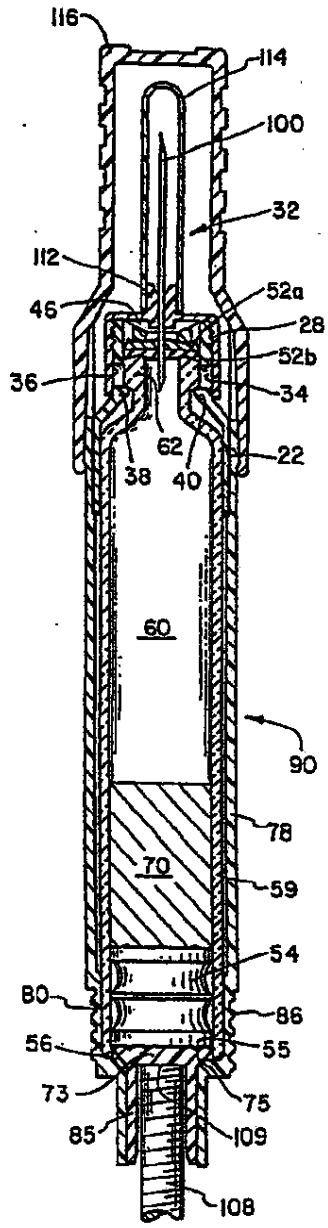
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FIG. 6

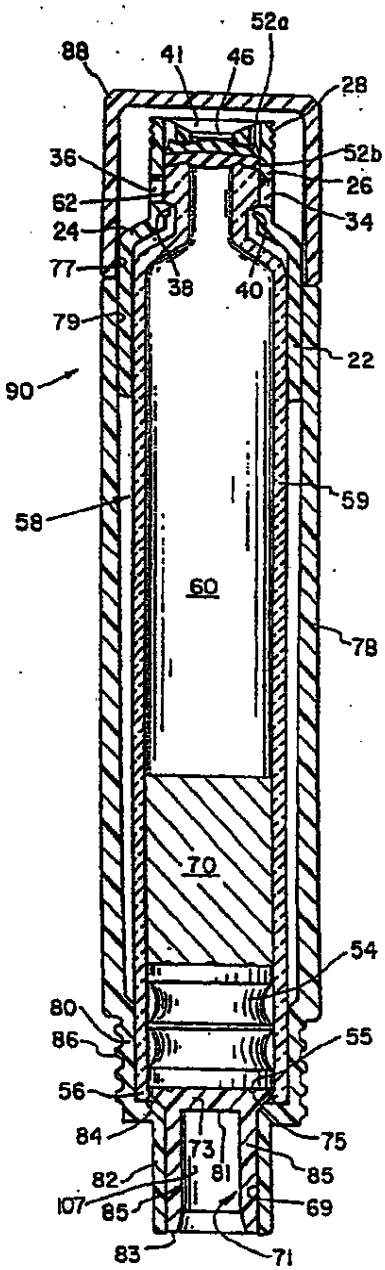
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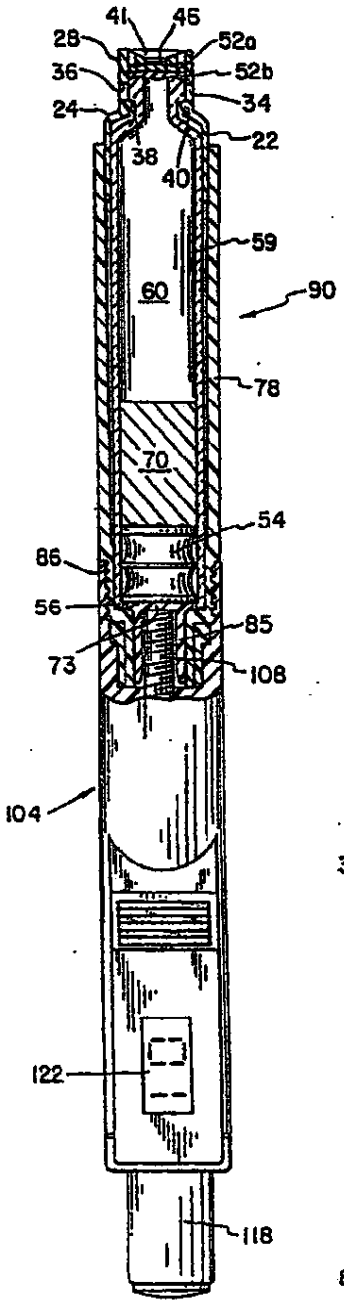
FIG. 7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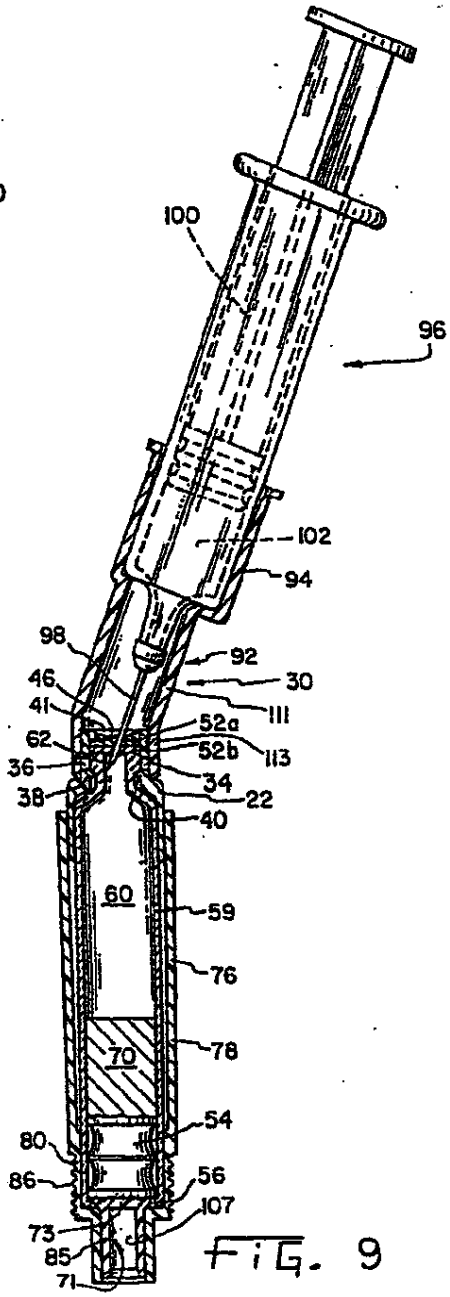
122
118

FIG. 8


100
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52b
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FIG. 9

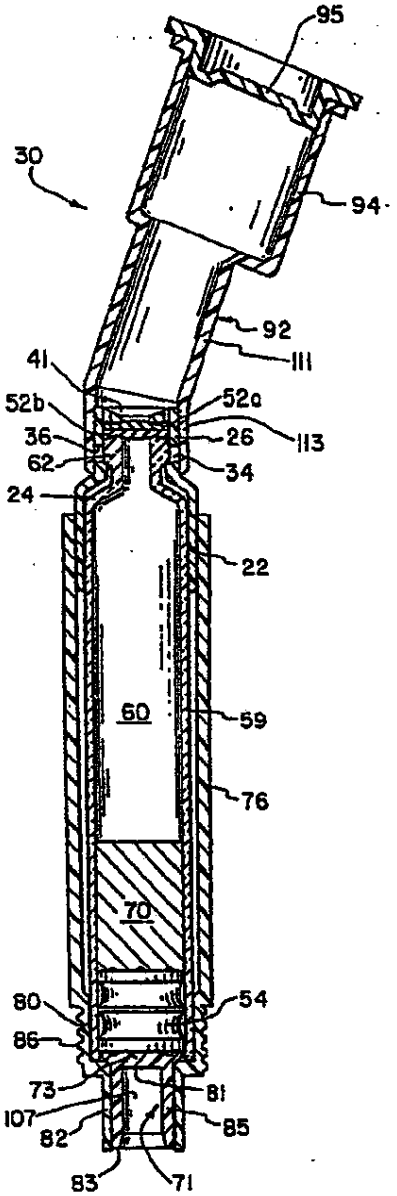
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FIG. 10

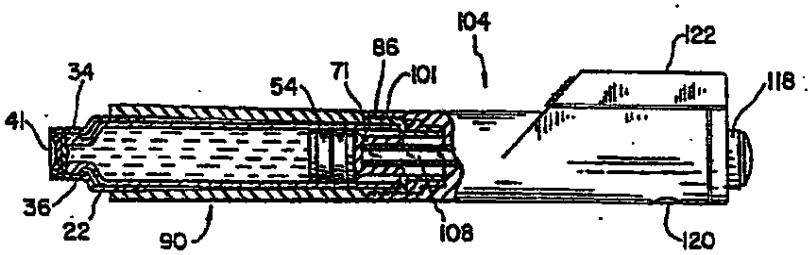

FIG. 11

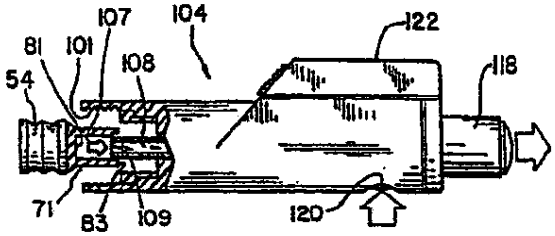

FIG. 12

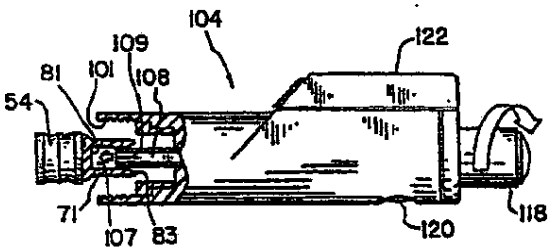

FIG. 13

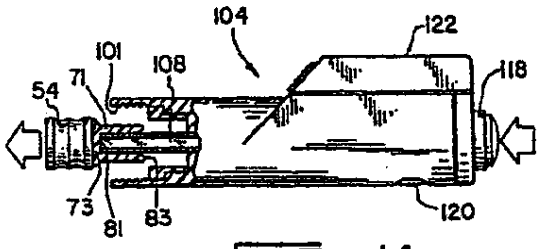

FIG. 14

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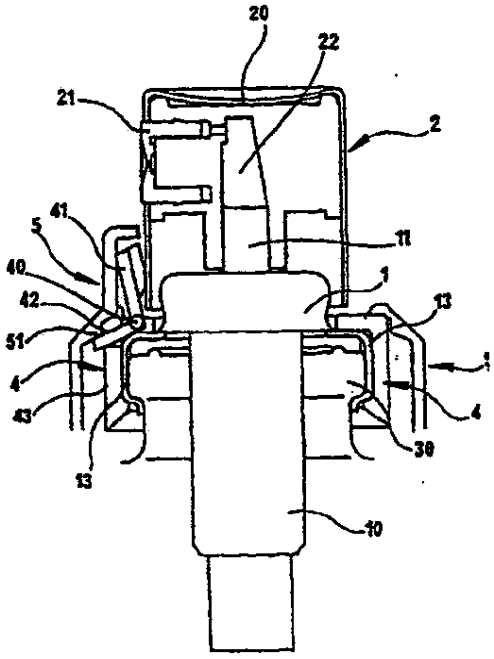
(54) Titre: DISPOSITIF DE DISTRIBUTION A SECURITE D'ACTIONNEMENT ET RECHARGE D'UN TEL DISPOSITIF

(57) Abstract

The invention discloses a dispensing device for a fluid product comprising a dispensing unit (1) provided with an axially movable control head (2) and a reservoir (3) containing the fluid to be dispensed, the said dispensing unit (1) being fixed on the reservoir (3), characterised in that the device further comprises means (4) for blocking any axial movement of the control head (2), and unlocking means (5) for engaging to the said blocking means (4) to cancel the action of the said blocking means (4) on the control head (2) and thus allow the axial movement of the said control head (2).

(57) Abrégé

Dispositif de distribution de produit fluide comprenant un organe de distribution (1) doté d'une tête d'actionnement (2) déplaçable axialement et d'un réservoir (3) contenant le produit fluide à distribuer, ledit organe de distribution (1) étant fixé sur le réservoir (3), caractérisé en ce que le dispositif comprend en outre des moyens de blocage (4) pour empêcher tout déplacement axial de la tête d'actionnement (2), et des moyens de déverrouillage (5) destinés à être mis en prise avec les moyens de blocage (4) pour effacer l'action desdits moyens de blocage (4) sur la tête d'actionnement (2) et ainsi permettre le déplacement axial de ladite tête d'actionnement (2).



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Dispositif de distribution à sécurité d'actionnement et recharge d'un tel dispositif.

La présente invention concerne un dispositif de distribution à sécurité d'actionnement ainsi qu'une recharge d'un tel dispositif. L'invention s'applique plus particulièrement au domaine de la parfumerie où le conditionnement du produit joue un rôle esthétique important. Le conditionnement peut représenter une certaine valeur et il est alors avantageux de pouvoir le rentabiliser. Des recharges peuvent alors être spécialement prévues pour ce type de conditionnement. L'application de l'invention dans le cadre d'un conditionnement réutilisable n'est qu'une mise en oeuvre préférentielle ; bien entendu, le dispositif de distribution à sécurité d'actionnement de l'invention peut être utilisé dans bien d'autres domaines tel que la cosmétique, la pharmacie, l'alimentation, la droguerie etc., sans application à un conditionnement réutilisable.

Il est déjà connu d'équiper certains dispositifs de distribution du type réservoir ou flacon muni d'un organe de distribution tel une pompe ou une valve, de sécurités d'actionnement ou de garanties de premier usage, afin d'assurer à l'utilisateur la primeur d'utilisation du dispositif. Ces sécurités ou garanties se présentent souvent sous la forme de bandes arrachables ou frangibles reliées à la tête d'actionnement du dispositif pour empêcher son actionnement. Une fois la bande arrachée ou détruite, la tête d'actionnement peut se déplacer axialement et distribuer le produit. Ce genre de sécurité ou garantie est basé sur le principe de l'immobilisation de la tête d'actionnement grâce à un élément à retirer ou à détruire.

L'arrachement ou la destruction de la bande nécessite une certaine force de traction qui peut parfois conduire au déchirement de la bande elle-même ; une partie de la bande reste alors en place, et il est difficile de la retirer complètement. En outre, la bande retirée constitue un déchet de petite taille dont il faut se débarrasser tout de même. Un autre inconvénient provient du fait que ce type de sécurité est irréversible, en ce sens que la bande ne peut plus être remise en place pour empêcher l'actionnement de la tête.

Un problème à la base de la présente invention est de réaliser un dispositif de distribution pourvu d'une sécurité d'actionnement fiable, non destructive, c'est-à-dire réversible, et dont la mise hors fonction s'effectue sans nécessiter une force particulière.

On connait déjà du document US-3 885 717 une sécurité à l'usage des enfants pour des bombes aérosols. La tête d'actionnement de la valve est pourvue de part et d'autre de pattes élastiques qui s'étendent vers le bas et dont les extrémités sont dotées de crochets qui viennent en prise sous la tête d'actionnement. Les pattes définissent ainsi ensemble un passage que le doigt doit obligatoirement emprunter pour accéder à la tête d'actionnement. Le doigt étant plus large que celui d'un enfant, seul le doigt d'un adulte est apte à s'engager dans le passage formé par les pattes élastiques en les repoussant de manière à dégager les crochets d'en dessous de la tête. Dans cette sécurité, le déverrouillage est effectué par le doigt de l'utilisateur et par conséquent tout adulte peut déverrouiller la bombe. Il ne s'agit donc pas d'une sécurité totale, mais uniquement sélective à l'égard des enfants. D'autre part, la largeur des doigts chez les adultes est très variable, de sorte que cette sécurité n'assure même pas la possibilité d'utilisation pour tous les adultes.

La présente invention a pour but de remédier à ces inconvénients en définisant une sécurité dite de premier usage non sélective dont le déverrouillage ne dépend pas de la nature de l'utilisateur.

Pour ce faire, il est prévu un dispositif de distribution de produit fluide comprenant un organe de distribution doté d'une tête d'actionnement déplaçable axialement et d'un réservoir contenant le produit fluide à distribuer, ledit organe de distribution étant fixé sur le réservoir, caractérisé en ce que le dispositif comprend en outre des moyens de blocage pour empêcher tout déplacement axial de la tête d'actionnement, et des moyens de déverrouillage pour effacer l'action desdits moyens de blocage sur la tête d'actionnement et ainsi permettre le déplacement axial de ladite tête d'actionnement. Les moyens de déverrouillage assurent la mise hors fonction des moyens de blocage qui restent en place sur le dispositif.

Avantageusement, les moyens de blocage comprennent au moins un élément de blocage disposé dans le chemin de déplacement axial de la tête d'actionnement, ledit élément de blocage étant écarté du chemin de déplacement axial de la tête d'actionnement par lesdits moyens de déverrouillage.

Selon une forme de réalisation, ledit au moins un élément de blocage est monté pivotant et comprend une surface de came, lesdits moyens de déverrouillage venant en prise avec ladite surface de came pour écarter par pivotement ledit élément de blocage hors du chemin de déplacement axial de la tête d'actionnement.

De préférence, les moyens de blocage comprennent plusieurs éléments de blocage répartis à espacement angulaire régulier tout autour de la tête d'actionnement.

Alors que la mise hors fonction de la sécurité de l'art antérieur constituée d'une bande est simplement

réalisée par son arrachement ou sa destruction, dans la présente invention, les éléments de blocage sont écartés par pivotement sans destruction de sorte que le retrait des moyens de déverrouillage permet à nouveau aux éléments de blocage de reprendre leur position initiale dans le chemin de déplacement de la tête ; ceci assure la réversibilité de la sécurité d'actionnement.

Selon une forme pratique, les moyens de blocage se présentent dans la forme d'une bague de blocage montée fixement sur l'organe de distribution ou le réservoir, ladite bague de blocage étant pourvue à son extrémité supérieure desdits éléments de blocage pivotants, lesdits moyens de déverrouillage se présentant sous la forme d'une bague de déverrouillage rapportée sur la bague de blocage en sollicitant les éléments de blocage par pivotement vers l'extérieur hors du chemin de déplacement de la tête d'actionnement.

Les moyens de déverrouillage sont rapportés sur les moyens de blocage avec lesquels ils viennent ainsi en prise pour effacer leur action. De plus, les moyens de déverrouillage agissent sur les moyens de blocage indépendamment de l'actionnement de la tête d'actionnement. Le déverrouillage n'est pas effectué par le doigt de l'utilisateur comme dans le document US-3 885 717 mais par un organe rapporté qui n'agit sur la tête d'actionnement.

Selon une caractéristique très avantageuse de la présente invention, le dispositif comprend en outre un étui dans lequel le réservoir est introduit, les moyens de déverrouillage connectant ledit étui de manière démontable, de sorte que le réservoir équipé de son organe de distribution peut être introduit et extrait de l'étui en tant que recharge, la connexion des moyens de déverrouillage sur l'étui mettant lesdits moyens de

déverrouillage en prise avec les moyens de blocage pour les déverrouiller.

Dans cette application préférentielle de l'invention, le réservoir équipé de son organe de distribution constitue une recharge pour un étui dont la partie supérieure de fermeture est constituée par les moyens de déverrouillage qui opèrent à la fois le déverrouillage des moyens de blocage et la fermeture de l'étui. Cette forme de réalisation est particulièrement avantageuse, car l'utilisateur n'a même pas besoin d'effectuer une opération particulière pour effacer l'action des moyens de blocage qui se fait automatiquement lors de l'encliquetage des moyens de déverrouillage sur l'étui.

Ainsi, il n'est même pas nécessaire d'informer l'utilisateur que la recharge incorpore une sécurité d'actionnement. De plus, si l'utilisateur souhaite bloquer l'actionnement du dispositif pendant un certain temps, il lui suffit de retirer légèrement les moyens de déverrouillage et les éléments de blocage reprendront leur place initiale sous la tête d'actionnement.

L'invention définit également une recharge de dispositif de distribution de produit fluide comprenant un organe de distribution doté d'une tête d'actionnement déplaçable axialement et d'un réservoir contenant le produit fluide à distribuer, ledit organe de distribution étant fixé sur le réservoir, caractérisé en ce que la recharge comprend en outre des moyens de blocage pour empêcher tout déplacement axial de la tête d'actionnement, lesdits moyens de blocage étant destinés à être déverrouillés à l'aide de moyens de déverrouillage faisant partie d'un ensemble de conditionnement destiné à recevoir ladite recharge. La recharge peut être achetée dans le commerce, équipée de sa sécurité d'actionnement, ce qui assure la primeur d'utilisation. L'ensemble de conditionnement est réutilisable et comprend un étui et

les moyens de déverrouillage qui viennent former l'étui en ne laissant passer que la tête d'actionnement.

L'invention sera maintenant décrite plus amplement en référence aux dessins joints, donnant à titre d'exemple non limitatif plusieurs modes de réalisation de l'invention.

Sur les dessins :

- la figure 1 représente la partie supérieure d'un dispositif de distribution selon l'invention avec les moyens de blocage en position de blocage, des moyens de déverrouillage étant omis,
- la figure 2 représente un dispositif de distribution de la figure 1 avec les moyens de déverrouillage en prise avec les moyens de blocage de manière à permettre le déplacement de la tête d'actionnement,
- la figure 3 représente une forme préférentielle de réalisation d'un dispositif de distribution selon l'invention, les moyens de blocage étant en position de blocage et les moyens de déverrouillage étant omis,
- la figure 4 est une vue du dispositif de distribution de la figure 3 avec les moyens de déverrouillage en prise avec les moyens de blocage de manière à libérer la tête d'actionnement dans son déplacement axial, et
- la figure 5 est une vue agrandie en coupe des moyens de blocage utilisé dans le dispositif de distribution représenté sur les figures 3 et 4.

En se référant d'abord aux figures 1 et 2, on voit que le dispositif de distribution selon cette première forme de réalisation ne représente que la partie supérieure du dispositif, seul le goulot 30 du réservoir étant représenté. Outre le réservoir qui peut être rigide ou souple, en matière plastique en verre ou en métal, le dispositif de distribution de l'invention comprend un organe de distribution désigné dans son ensemble par la référence numérique 1. Cet organe de distribution 1 qui

peut être une pompe ou une valve, comprend un corps de pompe 10 engagé dans le goulot 30 du réservoir. L'organe de distribution est serti par la partie supérieure de son corps 10 sur le goulot 30 à l'aide d'un sertissage 13. De manière classique, un joint peut être interposé entre le goulot 30 et le sertissage 13 pour assurer l'étanchéité du dispositif au niveau du goulot du réservoir. L'organe de distribution comprend en outre une tige d'actionnement 11 qui est montée coulissante dans le corps 10 de l'organe de distribution 1. La tige d'actionnement 11 est creuse et constitue ainsi un canal de refoulement du produit fluide mis sous pression dans le corps 10. Pour l'actionnement de la tige 11, il est prévu une tête d'actionnement désignée dans son ensemble par la référence numérique 2. La tête d'actionnement 2 comprend un canal interne 22 en communication avec l'intérieur de la tige d'actionnement 11 ainsi qu'avec un gicleur 21 destiné à pulvériser le produit fluide en fines gouttelettes. La tête d'actionnement 2 comprend également une surface de pression 20 adaptée à l'application d'un doigt par exemple. Une pression sur la surface 20 de la tête d'actionnement 2 amène la tête et la tige 11 à se déplacer axialement, comme on peut le voir sur les figures 1 et 2. Dans le cas d'une pompe, l'enfoncement de la tige 11 a pour effet de mettre la chambre de pompe comprise dans le corps de pompe 10 sous pression jusqu'à ce que le clapet de sortie de la pompe s'ouvre et refoule la dose de produit fluide à travers l'intérieur creux de la tige d'actionnement 11 jusqu'au gicleur 21 où la dose de produit fluide est pulvérisée. Dans le cas d'une valve, l'enfoncement de la tige de soupape 11 a pour effet de mettre en communication fluide l'intérieur du réservoir ou une partie de celui-ci avec l'extérieur à travers l'intérieur creux de la tige de soupape 11 jusqu'au gicleur 21 où le produit fluide est pulvérisé. Dans les

deux cas, qu'il s'agisse d'une pompe ou d'une valve, la distribution du produit fluide est réalisé grâce au déplacement axial de la tige d'actionnement 11 surmontée de son bouton poussoir 2 incorporant le gicleur 21.

Cette conception générale du dispositif de distribution selon l'invention est commune à toute les formes de réalisation décrite.

En se référant maintenant plus particulièrement à la figure 1, on voit que le goulot 30 du réservoir, ou plus précisément le sertissage 13 de l'organe de distribution, est recouvert par une pièce désignée dans son ensemble par la référence numérique 4 qui sert de moyen de blocage pour la tête d'actionnement 2. Cette pièce 4 réalisant un moyen de blocage comprenant une bague de blocage formée avec des pattes d'encliquetage 43 terminée par des dents d'encliquetage 46 qui sont en prise avec le goulot 30 du réservoir. Les pattes d'encliquetage 43 munies de leurs dents 46 permettent une fixation solide et stable de la pièce 4 sur le goulot 30. La bague de blocage 4 s'étend jusqu'au dessus du goulot 30 où elle est pourvue d'éléments de blocage 41 qui sont disposés dans le chemin de déplacement axial de la tête d'actionnement 2 pour bloquer la tête d'actionnement 2 en position de repos. Les éléments de blocage 41 sont répartis tout autour de la bague de blocage 4 dans le chemin de déplacement axial de la tête d'actionnement 2. Les éléments de blocage 41 peuvent au nombre de trois ou de six mais il est également envisageable de ne prévoir qu'un seul élément de blocage 41 sur la bague de blocage 4. Les éléments de blocage 41 sont montés pivotants sur la bague 4 autour d'un axe de pivotement 40. Pour permettre le pivotement des éléments de blocage 41, il est prévu une surface de came 42 qui est reliée à l'élément de blocage 41 de manière rigide de sorte qu'une pression exercée sur la surface de came 42 provoque le pivotement de l'élément de blocage 41 autour

de l'axe de pivotement 40. Comme on peut le voir sur la figure 1, les axes de pivotement 40 s'étendent de manière tangentielle à la bague de blocage 4, de sorte que la direction de pivotement de l'élément de blocage 41 s'étend radialement par rapport à la tige d'actionnement 11. Dans la position de repos de la bague de blocage 4, les éléments de blocage 41 sont disposés dans le chemin de déplacement axial de la tête d'actionnement 2. Afin d'assurer que les éléments de blocage sont correctement disposés en dessous de la tête d'actionnement 2, les éléments de blocage 41 sont pourvu d'un épaississement 410, qui augmente considérablement la surface de butée de l'extrémité inférieure de la tête d'actionnement 2 sur l'extrémité supérieure des éléments de blocage 41. Ainsi, grâce à l'interposition des éléments de blocage 41 en dessous de la tête d'actionnement 2, tout déplacement axial de la tête de et par conséquent de la tige d'actionnement 11, est empêché. Le dispositif de distribution ne peut alors pas être actionner de sorte qu'aucune dose de produit fluide ne peut être émise.

En se référant maintenant à la figure 2, il va être expliquer de quelle manière les éléments de blocage 41 sont déplacés hors du chemin de déplacement axial de la tête d'actionnement 2. Comme on peut le voir sur la partie gauche de la figure 2, les éléments de blocage 41 sont écartés hors du chemin de déplacement axial de la tête d'actionnement 2 à l'aide d'une bague de déverrouillage désignée dans son ensemble par la référence numérique 5. La bague de déverrouillage comprend une surface d'appui 51 qui coopère avec la surface de came 42 de l'élément de blocage 41 de manière à abaisser la surface de came 42. L'abaissement de la surface de came 42 provoque le pivotement de l'élément de blocage 41 vers l'extérieur en éloignement de la tige d'actionnement 11. La bague de déverrouillage 5 doit donc être emmanchée sur la bague de

blocage 4 jusqu'à ce que la surface d'appui 51 de la bague de déverrouillage 5 sollicite la surface de came 42 de l'élément de blocage 41 vers le bas. Le maintien en place de la bague de déverrouillage 5 peut être réalisée grâce à un encliquetage de la bague 5 sur la bague 4 ou sur une autre partie du réservoir. Ainsi, la mise en place de la bague de déverrouillage 5 sur la bague de blocage 4 a pour effet d'écarter les éléments de blocage 41 hors du chemin de déplacement axial de la tête d'actionnement 2. Comme visible sur la figure 2, la tête d'actionnement peut alors être déplacée vers le bas, ce qui a pour effet d'émettre du produit fluide par le gicleur 21.

Il est à noter que l'utilisation d'une bague de déverrouillage 5 pour effacer l'action des éléments de blocage préserve la réversibilité de la fonction de blocage des éléments de blocage 41 par simple retrait de la bague de déverrouillage. En effet en retirant la bague de déverrouillage 5, la surface de came 42 n'est plus sollicitée vers le bas par la surface d'appui 51 de la bague 5, ce qui a pour effet de faire pivoter les éléments de blocage 41 à nouveau dans le chemin de déplacement axial de la tête d'actionnement 2. Il est donc possible grâce à l'invention de remettre le dispositif de distribution à nouveau en sécurité par simple retrait de la bague de déverrouillage 5, ce qui n'était pas possible avec les dispositifs de sécurités ou de garanties de l'art antérieur qui impliquait une destruction des éléments de blocage.

En référence aux figures 3 et 4, il sera maintenant décrit un mode de réalisation et d'application préférentiel de la présente invention. Le caractère préférentiel tient plus à la mise en application du dispositif de distribution qu'à sa forme de réalisation particulière. Dans cette forme de réalisation et d'application, l'ensemble constitué du réservoir 3 et de

son organe de distribution associé 1 surmonté de la tête d'actionnement 2 constitue une recharge destinée à être placée dans un ensemble de conditionnement constitué d'un étui 7 enveloppant partiellement le réservoir 3, d'un manchon de liaison 6 et de la bague de déverrouillage 5. La recharge pourra être achetée dans le commerce déjà équipé de sa bague de blocage 4 assurant la sécurité de premier usage, afin de garantir la primeur d'utilisation à l'acheteur du produit. Tout comme la bague de blocage de la forme de réalisation des figures 1 et 2, la bague de blocage de cette forme de réalisation préférentielle est monté fixement sur un bossage périphérique annulaire réalisé par le goulot du réservoir 3 recouvert par le sertissage 13 de l'organe de distribution 1. Dans son état encore non monté dans l'ensemble de conditionnement, et disponible tel quel dans le commerce la recharge ne peut pas être actionnée en raison de l'interposition des éléments de blocage 41 en dessous de la tête d'actionnement 2.

En se référant maintenant à la figure 4, la recharge est représentée introduite dans un ensemble de condition dont la partie supérieure de fermeture est réalisée par la bague de déverrouillage 5. La bague de déverrouillage 5, comme dans le mode de réalisation représenté sur les figures 1 et 2, sollicite les éléments de blocage 41 par pivotement vers l'extérieur hors du chemin de déplacement axial de la tête d'actionnement 2. Le pivotement vers l'extérieur des éléments de blocage 41 est réalisé par appui de la bague de déverrouillage 5 sur les surfaces de came 42 solidaires des éléments de blocage 41.

Le détail de réalisation de la bague de blocage 4 sera décrit plus précisément en référence à la figure 5 ci-après. La bague de déverrouillage 5 coopère donc d'une part avec les surfaces de came 42 des éléments de blocage 41 ainsi qu'avec un manchon de transition 6 qui lui est

encliqueté dans l'extrémité supérieure ouverture de l'étui 7. La connexion de la bague de déverrouillage 5 sur l'extrémité supérieure du manchon de transition 7 peut être du type encliquetage, emmanchage en force ou même vissage. L'ensemble de condition réalisé par les éléments constitutifs 5, 6 et 7 recouvrent la totalité de la recharge à l'exception de la tête d'actionnement 2 qui doit rester accessible en vue de son actionnement.

Dans cette application en tant que recharge pour un ensemble de conditionnement réutilisable, l'effacement des éléments de blocage 42 est réalisé de manière automatique lors de la fermeture de l'ensemble de conditionnement en rapportant simplement la bague de déverrouillage sur le manchon de transition 6. Ainsi, en une seule opération l'ensemble de condition est reconstitué et la sécurité d'actionnement est effacée.

La figure 5 représente une section agrandie de la bague de blocage utilisée dans la recharge représentée sur les figures 3 et 4. La bague de blocage 4 est formée avec les pattes d'encliquetage 43 pourvues d'un évidemment périphérique annulaire 46 destiné à recevoir le bossage périphérique formé par le goulot 30 du récipient 3. Les pattes d'encliquetage 43 sont surmontées par les éléments de blocage 41 pourvus de leurs surfaces de came 42. Alors que dans la forme de réalisation des figures 1 et 2 le pivotement des éléments de blocage 4 était réalisé grâce à un axe de pivotement 40, dans cette forme de réalisation, le pivotement des éléments de blocage 41 est assuré par un pont de matière 45 qui relie les éléments de blocage 41 au restant de la bague. Les ponts de matière présentent une section réduite de manière à créer une zone de faiblesse définissant un point d'articulation. Le nombre d'élément de blocage 41 répartie tout autour de la bague de blocage peut être variable, mais en général ils seront au nombre de 3 à 6.

Revendications :

1.- Dispositif de distribution de produit fluide comprenant un organe de distribution (1) doté d'une tête d'actionnement (2) déplaçable axialement et d'un réservoir (3) contenant le produit fluide à distribuer, ledit organe de distribution (1) étant fixé sur le réservoir (3), caractérisé en ce que le dispositif comprend en outre des moyens de blocage (4) pour empêcher tout déplacement axial de la tête d'actionnement (2), et des moyens de déverrouillage (5) pour effacer l'action desdits moyens de blocage (4) sur la tête d'actionnement (2) et ainsi permettre le déplacement axial de ladite tête d'actionnement (2).

2.- Dispositif de distribution selon la revendication 1 dans lequel les moyens de blocage (4) comprennent au moins un élément de blocage (41) disposé dans le chemin de déplacement axial de la tête d'actionnement (2), ledit élément de blocage (41) étant écarté du chemin de déplacement axial de la tête d'actionnement (2) par lesdits moyens de déverrouillage (5).

3.- Dispositif de distribution selon la revendication 2 dans lequel ledit au moins un élément de blocage (41) est monté pivotant et comprend une surface de came (42), lesdits moyens de déverrouillage (5) venant en prise avec ladite surface de came (42) pour écarter par pivotement ledit élément de blocage (41) hors du chemin de déplacement axial de la tête d'actionnement (2).

4.- Dispositif de distribution selon les revendications 1 ou 2 dans lequel les moyens de blocage (4) comprennent plusieurs éléments de blocage (41) répartis à espacement angulaire régulier tout autour de la tête d'actionnement (2).

5.- Dispositif de distribution selon la revendication 4 dans lequel les moyens de blocage se présentent dans la

forme d'une bague de blocage (4) montée fixement sur l'organe de distribution (1) ou le réservoir (3), ladite bague de blocage (4) étant pourvue à son extrémité supérieure desdits éléments de blocage pivotants (41), lesdits moyens de déverrouillage se présentant sous la forme d'une bague de déverrouillage (5) rapportée sur la bague de blocage (4) en sollicitant les éléments de blocage (41) par pivotement vers l'extérieur hors du chemin de déplacement de la tête d'actionnement (2).

6.- Dispositif de distribution selon l'une quelconque des revendications précédentes, dans lequel les moyens de déverrouillage sont rapportés sur les moyens de blocage avec lesquels ils viennent ainsi en prise pour effacer leur action.

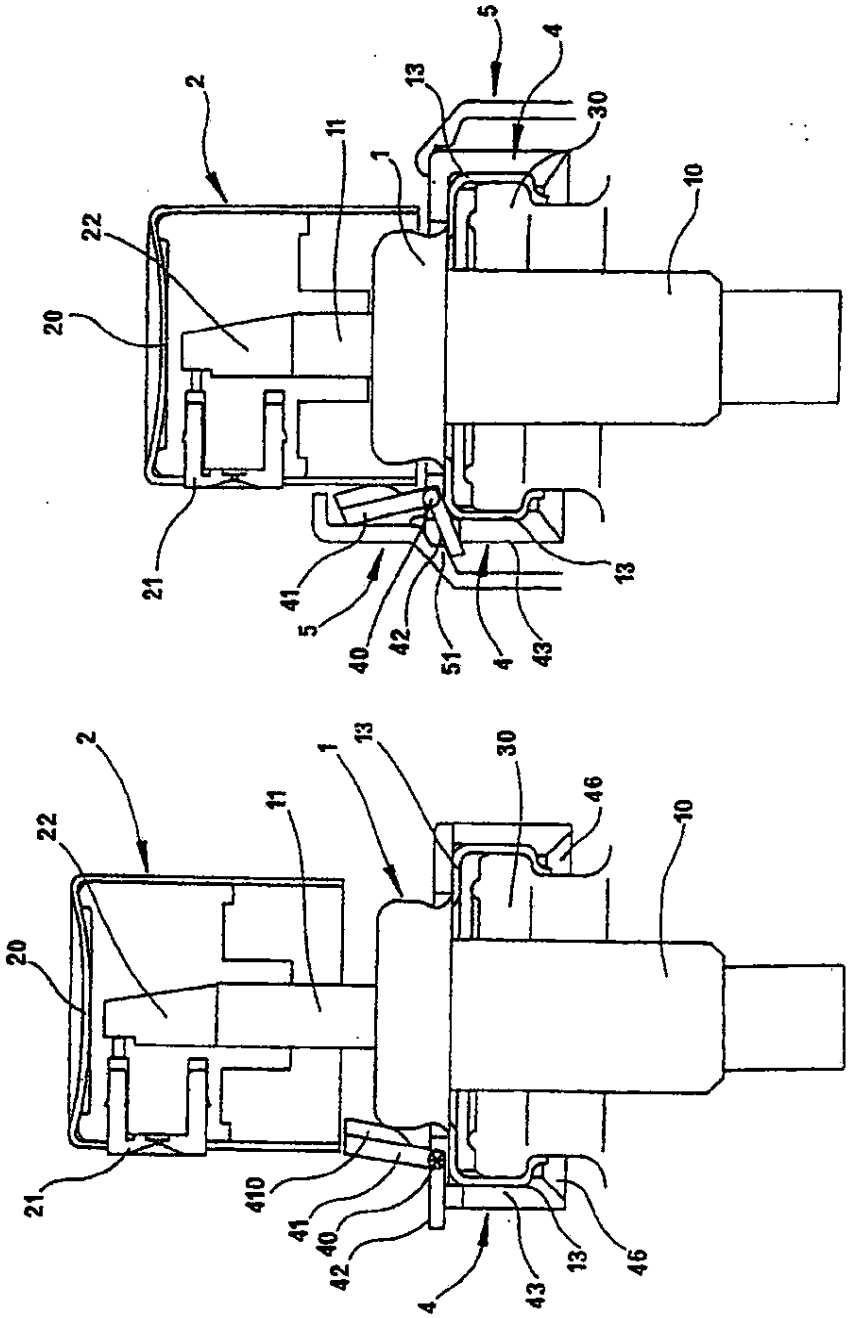
7.- Dispositif de distribution selon l'une quelconque des revendications précédentes, dans lequel les moyens de déverrouillage agissent sur les moyens de blocage indépendamment de l'actionnement de la tête d'actionnement.

8.- Dispositif de distribution selon l'une quelconque des revendications précédentes, dans lequel le dispositif comprend en outre un étui (7) dans lequel le réservoir (3) est introduit, les moyens de déverrouillage (5) connectant ledit étui (7) de manière démontable, de sorte que le réservoir (3) équipé de son organe de distribution (1) peut être introduit et extrait de l'étui (7) en tant que recharge, la connexion des moyens de déverrouillage (5) sur l'étui (7) mettant lesdits moyens de déverrouillage (5) en prise avec les moyens de blocage (4) pour les déverrouiller.

9.- Dispositif de distribution selon la revendication 8, dans lequel les moyens de déverrouillage (5) sont encliquetés sur l'étui (7), l'encliquetage opérant simultanément le déverrouillage des moyens de blocage (4).

10.- Recharge de dispositif de distribution de produit fluide comprenant un organe de distribution (1) doté d'une tête d'actionnement (2) déplaçable axialement et d'un réservoir (3) contenant le produit fluide à distribuer, ledit organe de distribution (1) étant fixé sur le réservoir (3), caractérisé en ce que la recharge comprend en outre des moyens de blocage (4) pour empêcher tout déplacement axial de la tête d'actionnement (2), lesdits moyens de blocage (4) étant destinés à être déverrouillés à l'aide de moyens de déverrouillage (5) faisant partie d'un ensemble de conditionnement destiné à recevoir ladite recharge.

1/2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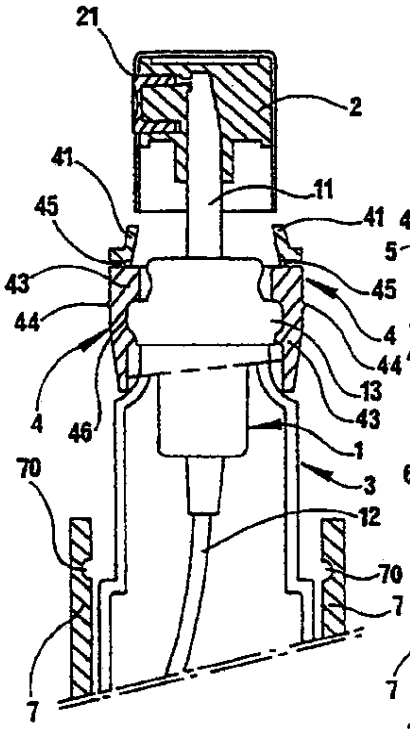

FIG.3

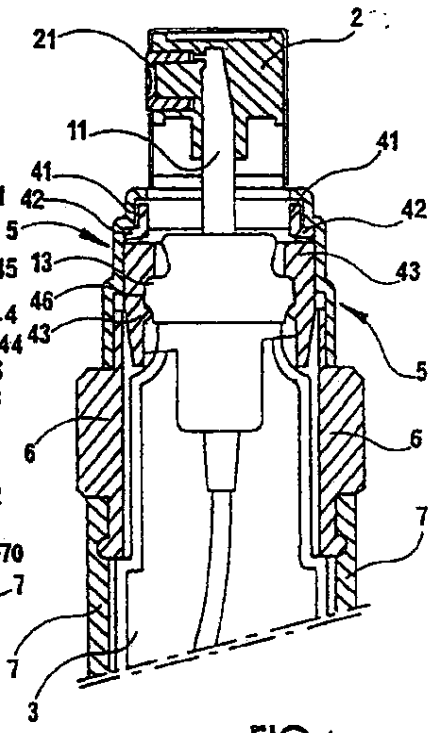

FIG.4

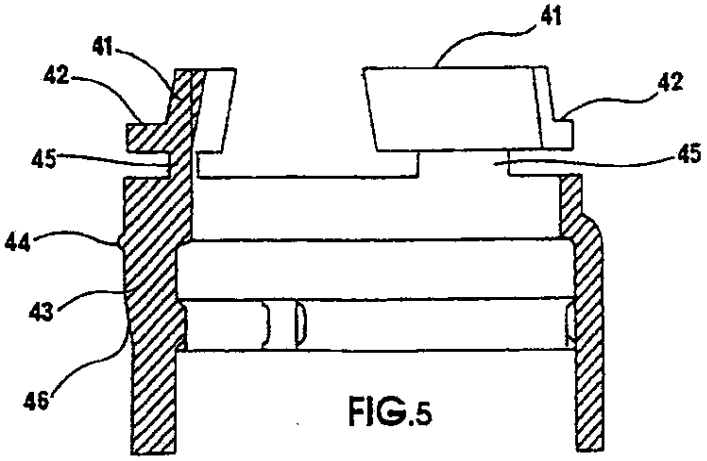

FIG.5

INTERNATIONAL SEARCH REPORT

Inter...nal Application No
PCT/FR 97/01064

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 B65D83/14 B05B11/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 B65D B05B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 3 885 717 A (EWALD RONALD F) 27 May 1975 see column 5, line 37 - column 5, line 53 see figures 5,6	1,10
A	US 3 606 106 A (YUHAS EDWARD R) 20 September 1971 see column 1, line 33 - column 2, line 23 see figures 1,2	1,10
A	EP 0 168 285 A (TELEPLASTICS IND) 15 January 1986 see abstract see figures 4,4A	1,10

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

1

Date of the actual completion of the international search	Date of mailing of the international search report
5 September 1997	10.09.97

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+ 31-70) 340-2040, Tx. 31 651 epo nl, Fax (+ 31-70) 340-3016	Farizon, P

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Information on patent family members

Inte. .onal Application No
PCT/FR 97/01864

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 3885717 A	27-05-75	CA 1014121 A	19-07-77
		DE 2418720 A	31-10-74
		FR 2226330 A	15-11-74
		GB 1442607 A	14-07-76
		GB 1442606 A	14-07-76
		NL 7400450 A	22-10-74
		US 4017009 A	12-04-77
		US 3786968 A	22-01-74
US 3606106 A	20-09-71	NONE	
EP 0168285 A	15-01-86	FR 2565799 A	20-12-85
		DE 3562007 A	05-05-88
		US 4676408 A	30-06-87

Form PCT/ISA/210 (patent family annex) (July 1992)

RAPPORT DE RECHERCHE INTERNATIONALE

Dem. internationale No
PCT/FR 97/01064

A. CLASSEMENT DE L'OBJET DE LA DEMANDE
CIB 6 B65D83/14 B05B11/00

Selon la classification internationale des brevets (CIB) ou à la fois selon la classification nationale et la CIB

B. DOMAINES SUR LESQUELS LA RECHERCHE A PORTE

Documentation minimale consultée (système de classification suivi des symboles de classement)
CIB 6 B65D B05B

Documentation consultée autre que la documentation minimale dans la mesure où ces documents relèvent des domaines sur lesquels a porté la recherche

Base de données électronique consultée au cours de la recherche internationale (nom de la base de données, et si cela est réalisable, termes de recherche utilisés)

C. DOCUMENTS CONSIDERES COMME PERTINENTS

Catégorie *	Identification des documents cités, avec, le cas échéant, l'indication des passages pertinents	no. des revendications visées
A	US 3 885 717 A (EWALD RONALD F) 27 mai 1975 voir colonne 5, ligne 37 - colonne 5, ligne 53 voir figures 5,6	1,10
A	US 3 606 106 A (YUHAS EDWARD R) 20 septembre 1971 voir colonne 1, ligne 33 - colonne 2, ligne 23 voir figures 1,2	1,10
A	EP 0 168 285 A (TELEPLASTICS IND) 15 janvier 1986 voir abrégé voir figures 4,4A	1,10

☐ Voir la suite du cadre C pour la fin de la liste des documents

☒ Les documents de familles de brevets sont indiqués en annexe

* Catégories spéciales de documents cités:

"A" document définissant l'état général de la technique, non considéré comme particulièrement pertinent

"E" document antérieur, mais publié à la date de dépôt international ou après cette date

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"T" document ultérieur publié après la date de dépôt international ou la date de priorité et n'appartenant pas à l'état de la technique pertinent, mais cité pour comprendre le principe ou la théorie constituant la base de l'invention

"X" document particulièrement pertinent; l'invention revendiquée ne peut être considérée comme nouvelle ou comme impliquant une activité inventive par rapport au document considéré isolément

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"&" document qui fait partie de la même famille de brevets

1

Date à laquelle la recherche internationale a été effectivement achevée	Date d'expédition du présent rapport de recherche internationale
5 septembre 1997	10.09.97

Nom et adresse postale de l'administration chargée de la recherche internationale	Fonctionnaire autorisé
Office Européen des Brevets, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+ 31-70) 340-2040, Tx. 31 651 epo nl, Fax (+ 31-70) 340-3016	Farizon, P

Formulaire PCT/ISA/210 (deuxième feuille) (juillet 1992)

RAPPORT DE RECHERCHE INTERNATIONALE

Renseignements relatifs aux membres de familles de brevets

Dem. internationale No
PCT/FR 97/01064

Document brevet cité au rapport de recherche	Date de publication	Membre(s) de la famille de brevet(s)	Date de publication
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Formulaire PCT/ISA/210 (annexe familles de brevets) (juillet 1992)